MATERNAL DEPRESSION IN KHAYELITSHA, SOUTH AFRICA: A COMPARISON OF HEALTH UTILISATION COSTS OF MATERNAL DEPRESSION AND THE COST OF INTERVENING THROUGH A TASK-SHIFTING APPROACH.

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PART 0: PREAMBLE

Plagiarism declaration

I, Stacy Kwamboka Orangi, hereby declare that the work on this dissertation/thesis is based on my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Dedication

I would like to dedicate my thesis to my parents and three sisters who have all shown me great support and encouragement throughout this whole journey. I would also like to appreciate my friends for their words of encouragement and thank God for giving me strength, knowledge and determination.

Thesis Abstract

This study assessed the health service utilisation costs of untreated maternal depression in women early in their pregnancy in Khayelitsha, South Africa. In addition, it determined the costs of providing treatment or support to these women through a psychological intervention that was delivered by trained community health workers. This thesis was a sub-study of the AFFIRM study (Africa Focus on Intervention Research for Mental Health) whose main objective was to determine the effectiveness, acceptability, cost-effectiveness and potential sustainability of a task-shifted psychological intervention offered to depressed mothers. To determine the costs of maternal depression, health care costs were analyzed over a period of 3 months from both patient and provider perspectives; this information was obtained from participants during their first antenatal visit. These health service costs (excluding antenatal and well-baby visits) were compared between psychologically distressed pregnant women with different severity levels of depression; no depression, mild depression and moderate/severe depression. The cost of the task-shifted intervention was calculated from a provider's perspective and compared to the costs of the 'enhanced usual care' that was offered to women in the control arm. The main costs that were analyzed were the costs of screening, start-up costs, costs of the rooms and recurrent costs. Sensitivity analyses were conducted to determine the robustness of the study results.

The results show that as the severity of maternal depression increases, the use of health services also increases. The health service utilisation costs among women with moderate/severe depression ($128.27 per mother/child pair per 3 month period) were almost seven times those of women who did not have depression ($19.70 per mother/child pair), amounting to a mean cost difference of $108.57.

For the intervention, salaries, followed by screening costs were the major cost drivers, with screening costs amounting to $26.69 per mother screened positive. Assuming the intervention was delivered to completion without loss to follow up, the cost per mother for the intervention was $230.47 in comparison to $69.93 per mother for enhanced usual care. A sensitivity analysis showed that the screening costs were sensitive to the prevalence of maternal depression.

From this study, it can be concluded that women with maternal depression use more health services and incur higher health care costs. It is possible to provide support to these women using psychological approaches that are delivered by lower level staff such as community health workers. This treatment can be affordable, depending on the budget constraints.

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PART A: PROTOCOL

Purpose of the study

Aim 1:

To assess the cost of depression among pregnant women who are psychologically distressed, comparing those who have no depression, mild depression and moderate/severe depression.

Objectives:

- To estimate the utilisation of a range of health care services (excluding antenatal and well-baby services) by mothers and their children over a period of 3 months for hospital admissions and outpatient visits prior to the first antenatal visit.
- Through costing these services, to assess the differences in provider and patient costs for pregnant women across the different severity levels of depression.

Aim 2:

To assess the provider costs of supporting depressed pregnant women.

Objectives:

- To calculate the provider costs of a psychological intervention provided by community health workers (CHWs)
- To calculate the provider costs of an 'enhanced usual care' intervention provided by CHWs

Background

Mental illness is defined as "a clinically significant disturbance in cognition, emotion regulation or behaviour that indicates a dysfunction in mental functioning that is usually associated with significant distress or disability in work, relationships or other areas of functioning" (American Psychiatric Association 2013). Major depression is a form of mental illness that affects the mood. Depression disorders in general are the leading cause of burden of disease globally, highlighting the need for inclusion of depressive disorders as a global health priority (Ferrari et al. 2013).

Depression is also the most common mental health condition to affect both perinatal women and mothers worldwide (Hanlon 2013). Maternal depression is a broad term for a range of depressive conditions that can affect a mother during pregnancy and up to 12 months post-partum (National Institute for Health Care Management 2010).

Maternal depression among other mental disorders affecting women of child bearing age not only brings mental suffering, but is a huge public health problem. This is because mental disorders in women lead to increased maternal mortality through adversely affecting the physical needs of the mother and directly through suicide (World Health Organisation 2008). In addition, maternal depression may be a risk factor for HIV infection and progression. This is because mental illness has been associated with reduced ability to practice safe sex as well as potentially lowering adherence to antiretroviral therapy (Collins et al. 2006). Maternal depression is also associated with adverse outcomes for the infant such as malnutrition, low birth weight, child development problems, and increased infant illnesses, amongst others (Anoop et al. 2004; Hadley et al. 2009; Ross et al. 2011).

Globally, mental disorders form the third leading cause of disease burden among women aged 14-44 years (Honikman et al. 2012). In low and middle income countries (LMIC) although variations exist within different settings, it is estimated that about 16% of women encounter depression during pregnancy and 20% encounter depression during the postnatal period (Hanlon 2013). On the basis of these findings, it is estimated that maternal mental disorders are three times more prevalent in LMICs than in high income countries (Honikman et al. 2012).

Maternal depression in South Africa

Community based epidemiological studies in South Africa have shown high prevalence rates of maternal depression. In rural KwaZulu-Natal, 47% of pregnant women in their third trimester were diagnosed with depression (Rochat et al. 2011). Another study done in Cape

Town in an informal settlement showed that 39% of pregnant women screened positive for depression while 35% of mothers were diagnosed with postnatal depression (Honikman et al. 2012; Cooper et al. 1999).

In South Africa, the vulnerability towards depression in pregnant women can be explained by a number of factors which include: the HIV/AIDS epidemic, violence, lack of social support, substance misuse, refugee status, teenage pregnancy and poverty which confounds all the previous factors (The Mental Health and Poverty Project 2010). Maternal depression as a result leads to poor uptake of services for these mothers.

Given the burden of disease of maternal depression and its consequences discussed above, it is arguable that more attention should be placed on maternal depression in South Africa; however, this is not the case. Antenatal services in South Africa include three visits and cover about 92% of pregnant women with the main focus being physical examination rather than emotional health (Honikman et al. 2012). After delivery, focus shifts to the infant. This suggests that despite the high levels of maternal depression in South Africa, there is no routine screening and treatment offered. Maternal depression is therefore overlooked and underdiagnosed as there is a lack of integration of maternal mental health into the antenatal services offered at primary care level (Manikkam & Burns 2012). In the next section, we look at the possible treatment approaches available for maternal depression.

Treatment and task shifting approach

Prompt accurate diagnosis and appropriate treatment is important for maternal depression to enable quick recovery and to prevent future episodes and as a result reduce the risk to the mother and infant (Sit et al. 2006). There are guidelines that have been produced by the WHO Mental Health Gap Action Programme (mhGAP) that include treatment guidelines for depressed pregnant women and postnatal mothers (World Health Organization 2010). For moderate to severe depression, prescription medication is recommended; however, for

pregnant women and breast feeding mothers, it becomes complicated and they would need extra support from their psychiatrists (Hanlon 2013). Furthermore, many women would be sceptical to take these medications during pregnancy and breastfeeding and as a result acceptability and adherence may be low. It could therefore be more appropriate to use psychological approaches instead which may be more acceptable to a majority of women (Hanlon 2013).

Psychological approaches can be broadly defined as mental health interventions that are strengthened by psychological methods and theory and are intended to improve the psychosocial functioning of the patient through delivery via a therapeutically structured relationship (Smith 2012). Examples of these psychological interventions include cognitive behavioural therapy, interpersonal therapy, and problem-solving therapies amongst others (Australian Institute of Professional Counsellors 2015).

Psychological approaches have been evaluated in postpartum low-income mothers in China and Chile (Jiang et al. 2014; Rojas et al. 2007). In both these studies, a psychological approach in the treatment of postnatal maternal depression was found to be effective in reducing depressive symptoms if there was good maternal compliance (Jiang et al. 2014; Rojas et al. 2007). Similarly, in Turkey, a pre-test-post-test mutual controlled semi-experimental model was used to determine the effect of a problem solving training intervention for post-partum depressed women offered by nurses and it was found to be effective at the primary health care level (Tezel & Gözüm 2006).

As much as a psychological approach is a good intervention, with a lack of resources to implement it, it would not be effective. In South Africa the mental health expenditure by the government is unknown (World Health Organisation 2011). However, it is reported that most African countries spend less than 1% of the total health budget on mental health (Dovi 2013). In addition to the limited budget allocated to mental health, there is a scarcity of psychiatrists

and psychologists - with 0.27 psychiatrists and 0.31 psychologists available per 100,000 population (World Health Organisation 2011).

It is in light of the issue of lack of sufficient resources for mental health that a task shifting approach has been recommended by the WHO and others (World Health Organization 2008c; Kakuma et al. 2011). A task shifting psychological approach is also more practical as services that were previously provided by mental health specialists are delivered by trained non-specialist health professionals under appropriate supervision (Hanlon 2013).

Pilot studies have been conducted in South Africa and Zimbabwe with regards to delivering problem-solving therapy (PST) using a task shifting approach and it has been found to be reasonably effective in reducing depressive symptoms (van't Hof et al. 2011; Chibanda et al. 2011). Despite the evidence from the pilot studies, randomised controlled trials (RCTs) are needed to evaluate the effects of PST or other psychological interventions on mental health more rigorously (van't Hof et al. 2011). A RCT conducted in a low-income area of Pakistan found that cognitive behavioural therapy offered using a task shifting approach for the treatment of perinatal depression was effective in reducing depression symptoms; fewer episodes of infant diarrhoea and more immunisations were other outcomes (Rahman et al. 2008). Another cluster RCT was conducted in rural India. In this study, the intervention was a women's group participatory intervention offered to depressed mothers who had given birth during the study period (Tripathy et al. 2010). This intervention involved the use of methods such as role-play, story-telling and games to help the mothers discuss the causes and effects of some of the problems that they face and as a group come up with strategies for prevention, homecare support and solutions to the issues. These meetings were facilitated by a local woman who underwent training to enhance her participatory communication techniques, with support from skilled health workers. The outcome of the study was a reduction in neonatal

mortality and a decrease in the maternal depression score (Kessler-10 item scale) in year 2 and 3 of the study (Tripathy et al. 2010).

Justification of the study

Research has shown that maternal depression is associated with higher health care costs (Petrou et al. 2002; Webster et al. 2001). Maternal depression not only affects health care expenditures but also results in lost productivity (News Editor 2012). This study will compare the health care costs of pregnant women among those with no depression, those with mild depression and those with moderate/severe depression according to the Hamilton Depression Rating Scale (HDRS): and obtain an incremental cost of depression (Zimmerman et al. 2013). In so doing, the study will provide health service utilisation costs of untreated maternal depression which would give policy makers a sense of the burden of maternal depression on the health system and the community.

Given the finding of the cost of untreated depression, informing policy makers on the costs of intervening through offering a task shifted psychological approach to depressed mothers would be relevant. However, most of the studies that have been done have focused on the effectiveness of the intervention offered (Rahman et al. 2008; van't Hof et al. 2011; Chibanda et al. 2011; Jiang et al. 2014; Rojas et al. 2007; Tezel & Gözüm 2006). There have been economic evaluation studies that have been done on psychological interventions but few have specifically focussed on maternal depression (Tripathy et al. 2010; Morell et al. 2009; Stevenson et al. 2010). The economic evaluations that have been done have focussed on psychological interventions for treatment of other conditions such as generalized anxiety disorder and secondary prevention of relapse after depression (Heuzenroeder et al. 2004; Rodgers et al. 2012). This study therefore hopes to add to the literature through reporting the results of a partial economic evaluation - a cost-analysis - of a task shifted psychological intervention offered in a low-income setting.

Africa Focus on Intervention Research for Mental Health (AFFIRM) study

This study is part of a larger randomized control trial, namely the AFFIRM study (Lund et al. 2014). Some of the data that are used for objective one of this study were collected by interviewing participants during their first antenatal visit as part of the broader AFFIRM study. The specific role of this MPH thesis is to estimate costs that will feed into the larger cost-effectiveness analysis for the AFFIRM study which will be undertaken once the trial and data collection have been concluded and the investigators are unblinded.

The overall aim of the AFFIRM study is to determine the acceptability, effectiveness, cost-effectiveness and potential sustainability of a task shifting approach for maternal depression compared to enhanced usual care. The participants that were randomly allocated to the intervention arm received 6 counselling sessions of approximately 1 hour in duration offered by trained CHWs. These sessions included structured manual-based psychosocial treatment with the four key foci being: psycho-education, problem solving, healthy thinking and behavioural activation. This intervention was informed by similar approaches used in this field, consultation with co-investigators as well as qualitative research conducted for the 12 months preceding the trial. On the other hand, participants who were randomized to the control group received enhanced usual care. The usual care consisted of antenatal and postnatal clinic visits where the main focus was on foetal and later infant development and immunisation. In addition to this usual care, enhanced usual care involved regular monthly phone calls over a period of 3 months that were delivered by CHWs. The phone calls involved brief conversations with the participant regarding (i) how the woman was feeling; (ii) whether there were any changes in the woman's life and if so what they were; (iii) whether she had someone to assist her if she needed help; (iv) whether she had been visited by CHWs from other non-governmental organisations (NGOs) and the nature of the visits; and (v) whether she had any suicidal ideations. If there were signs of suicide ideation, the

participant was referred to the psychiatric nurses in the clinic. If there were any problems such as abuse or other social problems, the participant would also be referred to relevant health services or NGOs.

Recruitment was done by trained field workers in collaboration with nurses from two study sites: Michael Mapongwana Community Health Centre Midwife Obstretics Unit and Site B Community Health Centre Midwife Obstretics Unit, both in Khayelitsha. The women included in the study were 18 years and older, living in Khayelitsha and isiXhosa speaking. An exclusion criterion from the study was any woman who had severe mental disorders such as schizophrenia, bipolar mood disorder or was experiencing an episode of psychosis. These participants were referred for further medical attention. Women meeting the inclusion criteria and who gave informed consent underwent a three stage screening process. Firstly, there was verbal confirmation from the participant to be included in the study. Secondly, the participant had to complete a set of demographic questions and lastly, the Edinburgh Postnatal Depression Scale (EPDS) was administered; those with a score of 13 and above in the EPDS were recruited into the study. After a power calculation to determine sample size, a sample of 420 women was deemed appropriate and a computer data management system was used to randomly allocate women to either of the two arms.

The outcome measure was the 17-Item HDRS . This primary outcome measure was assessed at baseline, and thereafter at three follow-up points: 1 month before delivery, and at 3 and 12 months after delivery. CHWs received weekly support and supervision from a specialist mental health counsellor, and checks were in place to ensure that burn out did not take place. In this study, participants were not informed of the hypothesis of the trial which is that mothers with depression who receive the task shifted care will have improved clinical outcomes, defined by reduction in depressive symptoms measured on the HDRS-17 at 3 months post-natal compared to the women receiving enhanced care.

In addition, the investigators and the field workers conducting the assessment were blinded to patient treatment and they worked independently of CHWs. The specialist mental counsellor and the CHWs were the only members of the project who were un-blinded.

This cost analysis and health service utilisation assessment is part of the AFFIRM study and hopes to feed into the larger RCT and cost-effectiveness analysis.

Methods

Economic evaluation: cost analysis

Economic evaluation is the comparative analysis of two or more alternative courses of action in terms of their costs and outcomes (Drummond et al. 2005). Economic evaluation is important because resources are scarce and decisions on how these limited resources might be efficiently allocated can be facilitated through the consideration of economic evaluation results (Slothuus 2000). Policy makers would be informed by such studies as to whether implementation of an intervention such as the task shifted psychological approach for depressed pregnant women would be worthwhile.

There are two major types of economic evaluation that can be employed: full economic evaluation and partial economic evaluation. Full economic evaluation includes cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA). In these full economic evaluations, the costs are identified, measured and valued in a similar manner; however, the nature of the outcomes are different and are therefore evaluated differently (Drummond et al. 2005). In CEA the outcomes are measured in natural units such as life years saved. On the other hand, CBA measures both costs and outcomes in monetary values while CUA measure the outcomes in utilities such as quality-adjusted life years (Drummond et al. 2005).

In this study, a partial economic evaluation was employed which is the cost-analysis. In a cost-analysis, only the costs involved in the two alternatives are evaluated; costs are not compared to outcomes. It is important to note that while a cost-analysis does not give any answers relating to efficiency, it is a relevant methodology for understanding affordability (National Institute of Health 2014).

Different perspectives can be taken within an economic evaluation (Mogyorosy & Smith 2005). A cost analysis - just like any other economic evaluation - can be conducted from either of three perspectives: provider perspective, patient perspective or societal perspective (Drummond et al. 2005). The provider perspective analyses costs incurred by the provider as a result of the intervention while the patient perspective only analyses costs that are incurred by the patient. The societal perspective is the broadest perspective and looks at all the costs incurred during the intervention both by the provider and the patients. Healthcare economic evaluation concerns the welfare of society and is based on welfare economic principles (Mogyorosy & Smith 2005). Mogyorosy & Smith (2005) therefore argue that a societal perspective should be adopted in economic evaluations because it is broader and allows the analyst to consider the impact of the use of resources outside the healthcare sector.

After the view point or perspective has been identified in a cost analysis, the different costs are identified, measured and valued. There are various definitions of cost: fixed costs are those that do not vary with the level of production over a short period of time e.g. rent, while variable costs are those that vary depending on the level of production e.g. supplies (Drummond et al. 2005;Mogyorosy & Smith 2005). Recurrent costs are those that are consumed within a period of one financial year, they may include direct costs and overhead costs. On the other hand, capital costs are those fixed assets that give economic benefit to the provider for a period of more than one financial year (Mogyorosy & Smith 2005). The capital

costs are an investment at a single point in time, and may depreciate in value with time (e.g. buildings or vehicles) or may be a non-depreciable asset (e.g. land).

Depending on the question and the purpose of the cost information, different costing approaches may be used. Drummond et al. (2005) give four different approaches to hospital costing including micro-costing, case-group mix, disease- specific per diem and average per diem. On the other hand Mogyorosy & Smith (2005), outline three costing approaches in economic evaluations which include a micro-costing approach, a gross-costing approach and a mixed approach . Costing is an exercise that takes considerable time and effort and it is up to the analyst to make a judgement call as to how accurate the cost estimates need to be depending on the availability of the data within a given study (Drummond et al. 2005).

Micro-costing, also known as the bottom-up approach (Mogyorosy & Smith 2005) entails a detailed identification of each resource and a unit cost is attached to each resource (Johnston et al. 1999). In addition, micro-costing is feasible where there is available data and is often conducted at a single centre or very few centres because of the extensive resources and coordination needed to collect the data (Frick 2009). On the other hand, gross-costing, also known as average per diem costs or the top-down approach, often uses routine facility expenditure data together with utilisation data (headcounts, inpatient days and outpatient visits) to arrive at an average cost across an organisational unit (Mogyorosy & Smith 2005). This approach assumes that there is only a small variation between patients and/or providers (Mogyorosy & Smith 2005). A mixed approach can also be used which is a combination of the top-down and bottom-up approaches. This can be used to cope with any missing data and/or collect data that is not routinely collected (Mogyorosy & Smith 2005). Table 3 below gives a summary of these costing approaches.

Table 1: Summary of the different costing approaches

Precision	Type of costing approach	Advantages	Limitations
Most precise	Micro-costing (bottom-up)	High level of precision Researcher can be quite certain about costs of a service	Quite expensive Highly burdensome Limited external validity
	Mixed approach	Cheaper than using only bottom-up approach More accurate than using only top-down approach Cost measurement tailored towards the study objective	Low external validity
Least precise	Gross- costing (top-down)	Fast and Cheap Can be the only feasible option (when complex hospital services are included)	Several assumptions which may affect the accuracy of the cost estimate Accuracy and reliability is highly dependent on the quality of secondary data Cannot be used to measure small changes in resource consumption.

Source: (Drummond et al. 2005; Mogyorosy & Smith 2005)

For determining the cost of depression, the costs of the health care services used by the mothers and their children (excluding antenatal and well-baby visits) are assessed using a gross-costing approach. Children are included because the adverse effects of maternal depression not only affect the mother but also their children. These costs have been obtained by examining the health care utilisation of the depressed mothers and their children as collected in a questionnaire administered to the clients during their first antenatal visit regarding any outpatient visits and hospital admissions in the recent past (within the last six months for inpatient admissions and within the last three months for outpatient visits). In gross costing the cost items are identified and broken up into large components (Mogyorosy & Smith 2005). It is the preferred method to use when not enough information is available to use the micro-costing approach, as is the case in this study when analysing the cost of depression (Mogyorosy & Smith 2005). These costs will be compared among women with

no depression, those with mild depression and moderate/severe depression classified by the HDRS.

A micro-costing approach has been used for the recurrent costs of the intervention. In this micro-costing, estimates of the time spent by CHWs and the mental health counsellor in providing the psychological intervention have been used. Micro-costing as mentioned above is more precise, reliable but more costly method to use as it requires more detailed resource utilisation measurements as compared to macro-costing (Mogyorosy & Smith 2005).

Capital costs according to Drummond et al (2005) are accounted for by annuitizing the initial capital outlay over the useful life of the asset. In this way, both the depreciation aspect and opportunity cost of the capital costs are incorporated and an 'equivalent annual cost' is derived.

Sensitivity analysis

In any economic evaluation, a sensitivity analysis is important in testing the robustness of the study's conclusion and to present the consequences of any inherent uncertainty of an evaluation on the results (Briggs 1995). In economic evaluation, uncertainty may relate to data requirements of the study, extrapolation of data or endpoints, generalizability of results and choice of analytic methods (Briggs 1995).

A simple sensitivity analysis is conducted by varying various components of the study to determine if there are major changes on the results of the costing analysis. In the sensitivity analysis, the percentage of people who screened positive for depression was varied. In addition, the discount rate was varied as well as the cost range of different cost-drivers of the intervention. This was done to test the robustness of the study results.

Study population and sample size

The study population includes participants screened positive for depression using the EPDS at Site B Community Health Centre Midwife Obstretic Unit and Michael Mapongwana

Community Health Centre Midwife Obstretics Unit, Khayelitsha. All participants who consented to be included in the AFFIRM study discussed previously were part of this study. A sample size of 420 participants was used with 210 participants in each of the intervention and control arms.

Estimation of costs

The different costs are identified, measured and valued. The costs analysed are:

(i) Health service utilisaton cost of untreated depression in pregnant women, based on their use of health care services (excluding antenatal and well-baby visits), and any direct non health care costs and indirect costs incurred. From this an incremental cost is derived for pregnant women with moderate/severe depression compared to pregnant women with no depression

(ii) Provider costs of both the task shifting psychological intervention for maternal depression as well as the costs of the enhanced usual care

The costs are estimated using 2014/2015 prices, salaries and financial year. The costs are reported in Unites States Dollars using an average exchange rate in the 2014/15 financial year (X-Rates 2015).

Cost of depression

Cost of depression is analysed from both the provider and patient perspective from data collected using a patient exit interview administered during the first antenatal visit when the pregnant women were approximately 4 months into their gestation period. From a provider's perspective, this included questions designed to elicit estimates of inpatient admission within the preceding 6 months and ambulatory service use (clinic visits, hospital outpatient, and private general practitioner visits) within the preceding 3 months for both the pregnant women and her children. Children are important to include in a cost of depression study

because they are directly affected by their mother's depression given the mother in most cases is their care giver.

The costs derived are compared between psychologically distressed mothers with different severity levels of depression which includes those with no depression, those with mild depression and those with moderate/severe depression according to the HDRS. The severity of depression is classified according to the score on the HDRS: those with no depression have a score of 0-7, those with mild depression have a score of 8-16 while those with moderate/severe depression have a score of 17 and above on the HDRS (Zimmerman et al. 2013).

As described above, a gross costing method is used to estimate the unit cost of each of the above mentioned services utilised by the pregnant women. These data were sourced from the Western Cape Department of Health Annual Report 2014/2015. This report provides information about total expenditure, numbers of inpatient days and numbers of outpatient vists at different levels of care. According to Health Systems Trust (2016) cost per patient day equivalent (cost/PDE) measures the average cost per patient, per day.

- PDE= Inpatients + ½ of day patients + 1/3 of outpatient & emergency room visit

Participants were not asked to identify the level of government hospital for admissions and hospital outpatient visits (e.g. district/tertiary); as a result, a cost per inpatient day and hospital outpatient visit is calculated for each level. Thereafter, a weighted average of the cost per inpatient day or hospital outpatient visit is derived using the proportion of PDE at each level of care.

The following formulae are used in these calculations:

- Average cost per inpatient day = Expenditure / [Inpatients + (Outpatient visits/3) + (hospital day patients/2)]

- Average cost per outpatient visit = Expenditure / [(Inpatient visits*3) + Outpatient visits + (hospital day patients*2)]

The outpatient cost is analysed from the responses given by the participants in the questionnaire. The participants are given five alternatives regarding where they sought medical attention: (i) their own home (ii) local health centre (iii) private general practitioner (iv) hospital outpatient (v) CHW's home. Due to unavailability of data to cost a health care visit either in the patient's own home or CHW's home, these two are assumed to cost the same as a visit to a local (primary level) health centre. In a similar manner as for hospitals, the average provincial primary health care expenditure per headcount is sourced from the Western Cape Department of Health Annual Report 2014/2015.

Private general practitioners typically charge user fees in South Africa, the out of pocket payments that the participants report for these visits served as a proxy for costs spent on private services.

Therefore from a provider's perspective:

Provider costs per mother/child for health services =

- Cost per mother or child for hospital admission(s) = (weighted average cost per inpatient day * number of inpatient days)
- Cost per mother or child for outpatient visit(s) = (weighted average cost per outpatient department visit* number of hospital outpatient visits) + (PHC expenditure per headcount* number of clinic visits) + (cost per general practitioner visit* number of general practitioner visits)

An incremental cost for health service utilisation is then calculated by obtaining the difference between the costs for the mothers with moderate/severe depression versus those who are psychologically distressed but have no depression.

From the patient's perspective, the out of pocket (OOP) expenditures of using the health care services will be analysed together with the travel and time costs.Time costs are derived by adding all the time spent seeking health care services (travel time, waiting time, consultation time and admission time) and multiplying this by the average income for the participants, taking into account the average number of working days in a month.

Patient costs per mother/child for health services =

- Cost per mother/child per hospital admission = OOP expenditures + time costs
- Cost per mother/child per outpatient visit = OOP expenditures + time costs + (travel costs * number of visits)

Direct costs of intervention and enhanced usual care from the provider's perspective

These include both recurrent and capital costs. Recurrent costs cover items that do not last for more than a period of a year. In this study, these include personnel costs such as CHWs and mental health counsellor salaries and costs of supporting CHWs. Costs of supplies such as training manuals and fidelity checks are also included. Operating costs for telephone services and stationary are also analysed. The unit costs of these recurrent costs are sourced from service providers and from the health facilities. A micro-costing approach is employed to calculate the recurrent costs for the intervention, whereby the quantity of resources used is multiplied by the market prices to obtain total costs.

Capital costs cover items that provide services for more than one year. These include the costs of the space in the building and furniture costs. These costs are annualised depending on the replacement value and at a discount rate of 8% (Walker & Kumaranayake 2002). These recurrent and capital costs are illustrated in Table 2 below.

Table 2: Recurrent and capital costs

Type of cost	**Identification** **Categories**	**Measurement**		**Valuation**	
		Costing method	**Source of data**	**Valuation method**	**Source of data**
Recurrent costs					
Screening costs	Training for those screening participants Salaries of those screening	Time spent in training or screening	Project records	Remuneration package costs	Provider expenditure reports
Personnel	CHW salaries Mental health counsellor salary	Percentage of time spent on counselling or phone calls or supervising the CHWs	Semi-structured interview with mental health specialist and records of CHWs	Remuneration package costs	Provider expenditure reports
Supplies	Training manuals/CDs/ workbooks Fidelity checks	Resources needed	Patient records or interview with providers	Market prices	Price lists
Operating and maintenance	Telephone costs and stationery costs	Actual costs from facility records	Financial records	Actual expenditure	Financial reports
Capital costs					
Buildings	Clinics	Size of room used for intervention		Replacement prices	Building prices
Equipment	Furniture and equipment used	Furniture used	Interview with clinic manager	Replacement prices	Local manufacturer
Training	Training of CHWs for 5 days	No. trained	Actual costs	Actual expenditure	Provider expenditure reports

From these direct costs, we have obtained the following costs that will be used to calculate cost per mother during the intervention period.

- Cost per person screened positive = [training costs + salaries] / number of participants screened positive
- Cost per counselling visit = [salaries of all staff + cost of supplies + operation costs + cost of training + equivalent annual cost of room + equivalent annual cost of furniture used] / number of visits
- Cost per telephone call = [salaries of all staff + operation costs + equivalent annual cost of telephone] / number of telephone calls

- Total intervention costs = Screening costs + [salaries of all staff + cost of supplies + operation costs + cost of training + equivalent annual cost of room + equivalent annual cost of furniture used]

The final sets of costs of the intervention that will be calculated are:

From a provider's perspective:

Intervention arm:

Cost per mother counselled (over six counselling sessions) = Cost per person screened positive + [Cost per counselling visit * number of visits]

Enhanced usual care:

- Cost per mother called (over 3 months) = Cost per person screened positive + [Cost per telephone call * Average number of calls made]

Ethical and legal considerations

The AFFIRM study poses minimal risk to the participant and obtained ethical approval from the University of Cape Town Human Research Ethics Committee (Ref no 226/2011) and the National Institute of Mental Health (NIMH) prior to the start of recruitment. A monitoring system is in place for adverse events and a protocol for the management of these events and reporting is in place. Participants in the AFFIRM study are asked about suicide ideation at all contact points for both the control and intervention arm. If any patient reports suicide ideation, a protocol is in place to refer them to a psychiatric nurse within the facility. Quality assessment of the study also occurs at several points in the study.

Dissemination of findings

The study results will be submitted to the principal investigator of the AFFIRM study for inclusion in future cost effectiveness analyses and the work is also likely to be published in a peer reviewed journal.

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PART B: LITERATURE REVIEW

Introduction

The objectives of this review are: (i) to give an overview of the consequences of maternal depression and the associated provider and patient costs (ii) to provide empirical evidence of the effectiveness of psychological interventions for maternal depression (iii) to provide an overview of task shifting as it relates to maternal mental health (iv) and to review published literature describing the economic evaluation of psychological interventions for maternal depression, so as to identify key gaps in the literature.

Studies that were included in this review were obtained from either Google Scholar, EBSCO HOST, Medline and PubMed, followed by a manual search on references of articles obtained from the above mentioned databases. Studies were reviewed if they included any type of psychological intervention for maternal depression as well as studies that reviewed the cost of untreated maternal depression or health service use patterns for depressed mothers and their children. Due to few studies done in this area, studies were included regardless of time frame and they ranged from the years 2001 to 2015. Studies conducted in low and middle income countries were the prime focus of this study but due to the limited number of studies in this setting, studies from high income countries were also included.

Overview of the consequences of maternal depression

The context of this study is Khayelitsha, the second largest township in South Africa with a majority of households living in shacks in informal settlements (Affordable Land and Housing Data Centre 2015). Such an area would be characterised by high maternal depression as research shows that depression is found to increase as income decreases (Schmit et al. 2014). Maternal depression is a public health problem that has consequences not only to the mother and the infant, but may lead to economic losses since the reproductive years (15-44 years) are also the most economically viable years (World Health Organization

2008). Maternal depression as well as any other type of depression can be as heavily disabling to the patient as any other chronic disease such as diabetes, hypertension and arthritis (Berto et al. 2000), yet it does not receive the same level of attention as the other chronic illnesses.

The consequences to the mother may include pre-term labour, complications during pregnancy, poor physical health of the mother, and increased risky behaviour which may include substance and alcohol use (World Health Organization 2008a). In addition, the deleterious effects of maternal depression can spill over to the infant. This can have effects that leads to compromised basic care-giving practices such as early discontinuation of breast feeding, few well baby visits and incomplete vaccinations given to the infant (Field 2010). As a result of the troubled mother-infant interaction, long term effects to the infant may include impaired cognitive and emotional development as well as behavioural disturbances later in life (Cooper & Murray 1998). As a result of these consequences, maternal depression has a significant burden on countries as a result of more medical resources that are needed and productivity losses incurred due to absenteeism at work, early retirement or mortality (Berto et al. 2000).

As a result of the consequences discussed above, maternal depression can destroy lives as the quality of life of the mother is not optimal. It is often said that "children are our future" (Bernad van Leer Foundation 2004) and this may be a phrase that could resound with women in Khayelitsha who hope that, through education, their children would be able to move out of poverty. However, this may not be the case if maternal depression is not addressed, because a child's development and the development of the society is greatly influenced by the first days, months and years of the child's life (Bernad van Leer Foundation 2004). By addressing maternal depression the health of the mother and child is improved, the relationship between the parent and child is restored and poverty may be decreased through

having women who are able to resume work and children whose cognitive development is not affected (Schmit et al. 2014). In addition, there may be impacts on relative health care utilisation, which is the subject of the next section.

Empirical evidence of health service utilisation in maternal depression

In non-puerperal depression (not related to child birth), there has been an association between depressed clients and an increase in health care service use (Webster et al. 2001). Given the consequences of maternal depression above, it is probable that maternal depression also leads to increased health service utilisation. Evidence of this is illustrated in Table 1 below.

Table 1: Health service utilisation in maternal depression

Author, Location	**Study participants**	**Time frame of costs or frequency of health service use**	**Costs considered or service utilisation considered**	**Perspective taken**	**Results**
(Petrou et al. 2002) United Kingdom	Women at risk of postnatal depression and their infants	Between delivery to 18 months postpartum	All health care utilisation costs and social care costs of mother and infant.	Provider's perspective	Women with postnatal depression incurred more costs for mother-infant health care use as compared to those with no depression
(Webster et al. 2001) Australia	Women who attended the antenatal clinic: Categorised as either having postnatal depression or not	First four months postpartum	Did not look at costs but rather health care use patterns of the mother	Not applicable	Women with depression were more likely to visit a psychiatrist, social worker, paediatrician, and general practitioner as compared to women with no depression.
(Farr et al. 2013) United States	Infants of mothers enrolled in the study: Categorised as having either prenatal depression, postnatal depression or no depression at all.	First year of the baby's life	Did not look at costs but rather health care use patterns (well baby visits, infant outpatient and emergency visits and infant hospitalisa-tion)	Not applicable	Infants of mothers with perinatal depression were as likely to attend well baby visits and immunisations Infants of mothers with postnatal depression had more outpatient/ emergency visits as compared to those of mothers with no depression and had an increased risk of hospitalisation.

Of the three studies reviewed in this section, two studies looked into the health care utilisation patterns of the mother alone (Webster et al. 2001) and infant (Farr et al. 2013) with postnatal depression and compared this to mothers and infants of mothers with no depression. The third study analysed the cost of health care use of the mother-infant pair with postnatal depression and compared it to the women with no depression (Petrou et al. 2002). From the two studies that analysed health service use patterns, it is evident that women with maternal depression would seek more health care either for themselves or their infants (Webster et al. 2001; Farr et al. 2013). The other study that analysed the costs of depression for both the mother and child reported higher costs incurred for the mother and infant pair with postnatal depression as compared to those with no depression (Petrou et al. 2002).

It can be argued that the increased health utilisation costs are as a result of depression specific treatments but Bock et al. (2014) found that the cost of mental health contributed very little to the total costs because the depressed clients rarely utilised mental health services in that study. It could be that the depressed clients do not seek timely care for any health care condition, and therefore when they do they may require longer and more intense care, resulting in higher costs (Bock et al. 2014). The economic burden as a result of maternal depression is evident and therefore efforts should be made to address maternal depression such as offering psychological interventions - as discussed in the next section.

Overview of psychological interventions

Psychological interventions are defined in general as a set of methods/practices that enable change in a person's thinking or behaviour through the use of various strategies including goal-setting, visualization, relaxation and other common techniques (Schwab Reese et al. 2012). There are different types of psychological interventions and an assessment is required to determine the best set of approaches that an individual or group needs (Black Dog Institute

2013). The AFFIRM (Africa Focus on Intervention Research for Mental Health) trial offers a psychological intervention for depressed mothers that includes aspects of psycho-education, problem-solving therapy, behavioural activation, cognitive reframing and relaxation training (Lund et al. 2014). This approach was informed by a review of available literature, that was conducted before the trial, that showed the need for problem solving skills, expanding social support and usual activities through behavioural activation and lastly the need for cognitive reframing as a result of negative persistent thoughts (Lund et al. 2014)

These different types of psychological interventions will be discussed in detailed below.

Cognitive behavioural therapy (CBT) or cognitive reframing is a psychological intervention that was developed by Aaron Beck in the 1960s. Beck argued that depressed clients experience a pattern of negative thoughts about themselves, the world and/or the future that arise extemporaneously (Beck Institute for Congnitive Therapy 2014). CBT - as a form of active, problem-structured and time limited therapy - is then understood to reduce these negatively biased beliefs and thoughts, which in turn is understood to reduce the severity of depression (Butler & Beck 1995). According to the Royal College of Psychiatrists (2015), CBT is defined as a way of talking about how one thinks about oneself, other people and the world and how actions affect thoughts and feelings. The focus of CBT is on problems that affect an individual now rather than focussing on the cause of the depression in the past (Royal College of Psychiatrists 2015). The general approach used in CBT involves directing clients through a number of structured learning experiences. The clients are then taught to identify, monitor and jot down their negative mental images or thoughts in order to recognize the association between their thoughts, feelings and behaviour (Butler & Beck 1995).

During CBT sessions, the counsellor is active and helps the individual or group make sense of overwhelming problems by breaking them into smaller, more manageable parts. A guideline is normally used by the counsellor and homework is given to the patient with the

aim of teaching the patient that their thinking is affected by their mood; thus a less negative outlook on life and themselves is important (Whitfield & Davidson 2007). These sessions help the clients develop coping skills and as time progresses, the clients learn to identify, evaluate and modify underlying flawed beliefs and assumptions that may have predisposed them to depression (Butler & Beck 1995). After 8 sessions, typically the clients have a reasonable level of mastery in the skills involved, although a full course of treatment is considered to encompass 14-16 full sessions with severe cases requiring more time (Butler & Beck 1995). CBT has been found to be the most effective psychological treatment for moderate and severe depression and for many types of depression it has been found to be as effective as antidepressants (Royal College of Psychiatrists 2015). By way of illustration Appleby et al. (1997) in a comparative study suggest that short-term CBT therapy is as effective as fluoxetine, an antidepressant drug.

Behaviour therapy, also known as behavioural activation, is another form of psychological intervention that is a major component of CBT discussed above. It is however different to CBT in that the focus is not on changing the attitudes and beliefs of the client but rather on increasing the level of activity of the client and the pleasure in their life (Jorm et al. 2009). For example this could include guiding clients to engage in activities that they find rewarding, either because they are pleasant to do or because they bring a sense of satisfaction (Jorm et al. 2009). In this way, behaviour therapy helps to reduce patterns of avoidance and withdrawal that are common in depression (Jorm et al. 2009). As mentioned earlier, behavioural activation is a large part of CBT and therefore few studies have been done that examine behavioural activation alone. In spite of that, there have been well-designed studies that have found that behavioural activation and CBT are equally effective in reducing depressive symptoms (Ekers et al. 2011). Ekers et al. (2011) argue that if behavioural

activation is equally effective to CBT, it would be the optimal strategy given the greater ease of delivery, the option to task shift to lesser trained professionals, and hence the lower cost.

Interpersonal therapy (IPT) focusses on interpersonal difficulties, recent life events and symptoms. In IPT, the main focus of the therapeutic attention is on interpersonal relationships with the aim of assisting the patient to work on and improve their interpersonal relationships or to modify their expectations about them (Robertson et al. 2008). This therapy is based on a framework which emphasizes that relationships are the most basic and important aspect of human experience and further points out that social problems or interpersonal conflict may cause depression (Swartz 2014). In IPT there is an association between onset or maintenance of depression and four categories of interpersonal problems which include grief, role dispute, role transition or interpersonal sensitivity (Robertson et al. 2008). In pregnancy, role transition is the major interpersonal challenge due to the changes the mother has to go through during this period. This therapy is therefore time-structured and would assist the depressed mother to form a realistic view of her previous role (which is normally seen as ideal) and the new role (which may be devalued) and develop coping strategies for the new role (Swartz 2014). There are no known risks of IPT and the length of treatment usually varies, ranging from 4-24 weeks (Jorm et al. 2009).

Problem solving therapy was described by D'Zurilla (1971) as a behavioural process that considers a number of alternatives for dealing with a particular problem and increases the probability of an individual selecting the most appropriate and effective response from among those alternatives (D'Zurilla & Goldfried 1971). This form of therapy involves clients learning new problem solving skills or re-activating old skills. It is suitable for common mental illnesses and has been found to be as effective as antidepressants in the treatment of depression (Pierce 2012). D'Zurilla & Goldfried (1971) identify stages in problem solving which include; (1) goal setting, (2) definition of the problem, (3) generating alternatives, (4)

decision making and implementation, and (5) verification or assessing the outcome. The clinician's role is to facilitate the stages of problem solving therapy in a chronological and organised manner and to implement the solution that the patient selects in order to empower the patient to solve the problem on their own (Pierce 2012).

Psycho-education is an intervention aimed at empowering clients through enhancing their awareness of the nature of their disease, through promoting proactivity and by giving the clients tools to cope, manage and live with the disease (Colom 2011). Psycho-education is intended to 'replace guilt by responsibility, helplessness by proactive care and denial by awareness' (Colom 2011).

Relaxation training is any process or method that helps a client attain an increased level of calmness by letting go of tension and helping the client relax (Fung & White 2012). It is mainly used as an add-on therapy and includes techniques such as guided imagery, deep breathing techniques and meditation among others (Fung & White 2012). It has been found to be a simple and low-cost intervention that can reduce depressive symptoms.

Theoretical overview of a task-shifting approach

The above approaches or types of psychological interventions can be used alone or in combination, and can be offered by mental health counsellors or can be delegated to other cadres. Task shifting refers to a strategy where tasks are delegated to health workers with shorter training and qualifications by more highly qualified health workers who would previously have carried out the tasks themselves (Patel 2009). Task-shifting is an approach to addressing the problem of scarce human resources that leads to high unmet needs for the treatment of mental illness, particularly in low and middle income countries (Wang et al. 2007). The scarcity of human resources is further exacerbated by the movement of health

workers from less developed to more developed countries (Mullan 2005) and from the public sector to the private sector.

Dovlo (2004) identifies four main categories of a task-shifting strategy: (1) delegation of the task to a different profession – for example a nurse taking up the tasks of a physician; (2) delegation of tasks from professionals to substitute health workers - for example a clinical officer carrying out the tasks of a physician; (3) delegation of specific roles to other less trained health workers of the same profession - for example a general practitioner carrying out the duties of a psychiatrist; (4) delegation of certain aspects of tasks in order to minimize work load such as administration of patient reports by ward clerks.

A task shifting approach aims to improve productive efficiency through achieving a given level of output with a less costly mix of inputs (Fulton et al. 2011). The costs of providing the appropriate health services through task shifting is not only lower from a provider's perspective, since the substitute health workers have lower qualifications and shorter training, but can also be less costly from a patients perspective if the substitute health workers are available in health facilities closer to the people (Zachariah et al. 2009).

However, one limitation of task shifting in a real world situation is the risk of inadequate supervision, support and training which would lead to sub-standard care being delivered to the patients by the lay worker (Lehmann et al. 2009). Of importance therefore, is that the quality of the services offered during task-shifting should be maintained. This can be achieved through continuing supervision, support and quality assurance offered by the professional (Patel 2009). World Health Organization (2007) proposes ways of ensuring quality in task shifting including defining training and experience needed, having examinations and mentoring procedures, offering opportunities for continuing education and mechanisms such as licensure, registration or accreditation to ensure quality assurance.

Psychological interventions can therefore be offered through a task-shifting approach; evidence of the effectiveness of such approaches are reviewed in the next section.

Effectiveness of psychological interventions for maternal depression and task shifting

This section provides evidence of the effectiveness of psychological interventions for the treatment of maternal depression. All studies found were included and this entailed evaluation of 11 studies. Nine were from low and middle income settings (Jiang et al. 2014; Tripathy et al. 2010; Tezel & Gözüm 2006; Rojas et al. 2007; Rahman et al. 2008; Gao et al. 2012; Baker-Henningham et al. 2005; Toth et al. 2013; Aracena et al. 2009) while two were from high income countries (Cooper et al. 2003; Milgrom et al. 2005). Given that the focus of this thesis is on maternal depression, studies that included maternal depression as an outcome measure (be it as a primary or secondary outcome) were considered.

The studies reviewed for this section employed different types and combinations of psychological intervention. Aspects of CBT and problem solving therapy were quite common and were used in six of the studies, while behaviour activation therapy and psycho-education were used in four of the studies. The less common psychological interventions employed in these studies were IPT and psycho-dynamic therapy which were included in three and one of the studies respectively. These details are summarized in table 2.

Nine of the studies showed that psychological interventions were more effective at decreasing the symptoms of maternal depression than routine care or enhanced usual care (Jiang et al. 2014; Rojas et al. 2007; Rahman et al. 2008; Gao et al. 2012; Baker-Henningham et al. 2005; Toth et al. 2013; Aracena et al. 2009; Cooper et al. 2003; Milgrom et al. 2005). In one of the studies, however, there was no difference in depressive symptoms between the intervention and control group by the second year, although some effectiveness was noted in reducing symptoms in moderate depression in the third year of the study (Tripathy et al. 2010). Tezel

& Gözüm (2006) compared a psychological intervention to nursing care for depressive symptoms. In the nursing care arm, a symptom checklist based on a nursing model was used during the first visit. Thereafter, a care plan was made on an individual basis offered over a 6 week period and outcomes were assessed. Tezel & Gözüm (2006) found that both interventions decreased maternal depression, but nursing care was more effective.

Despite the evidence of effectiveness for these psychological interventions, a number of difficulties were encountered. A number of studies noted limitations on the sustainability of the effectiveness once the period of the intervention was complete. According to Cooper et al. (2003) at 4.5 months postpartum, psychological interventions have the potential to reduce maternal depression symptoms, but at 9 and 18 months postpartum, these benefits had waned. This decrease in effectiveness with time was also seen in a study in Chile, where depressive symptoms were lower in the intervention than in the control at 3 months after the intervention was administered, but by 6 months the difference between the two arms had decreased (Rojas et al. 2007). This reduction in effectiveness is probably due to spontaneous remission of the disease (Cooper et al. 2003) . To ensure long term effectiveness, additional sessions may need to be offered less frequently on a long term basis.

Secondly, the duration of these studies was different and this may have had an impact on the outcomes. The duration in which interventions were offered varied from 6 weeks (Tezel & Gözüm 2006) to about 20 months (Tripathy et al. 2010).

In India, there were no significant effects from the intervention during the first two years of the study, however during the third year there was a decrease in moderate depression symptoms (Tripathy et al. 2010). Similarly, in Jamaica, the more the participant received the home visits, the more likely the mother would benefit from the intervention and have improved outcomes (Baker-Henningham et al. 2005). On the other hand, in Turkey, where a pre-test post-test mutual controlled experiment was conducted with the intervention being

offered for six weeks, decrease in depression was higher in the control arm (nursing care) than in the psychological intervention (Tezel & Gözüm 2006). This may suggest that either the nursing care for maternal depression is equally effective to a psychological intervention, or the intervention needed to be offered for a longer period of time. On the basis of these findings, it is suggested that the longer the intervention is offered, the more likely it is to have a positive, and sustained impact on maternal depression.

Thirdly, in these studies different screening tools were used to assess maternal depression. The different studies that were reviewed used different screening tools that were either clinician-rated scales or self-report questionnaires or a combination of both. This is illustrated in Table 2 below.

According to Boyd et al. (2005) the available literature is limited but shows a wide variability, which implies that there is little evidence to support the choice of appropriate screening tool for postpartum depression. This could be the reason why there was a wide array of screening tools used in these studies.

The use of different screening tools, different types of psychological interventions and different approaches to offer the intervention (both in terms of frequency and duration) makes it difficult to compare these studies to each other. Nevertheless, these studies do suggest that there is evidence pointing towards the effectiveness of psychological interventions in reducing maternal depression symptoms.

Table 2: Summary of studies on the effectiveness of psychological interventions on maternal depression

Author, experimental design & location	Study participants	Description of intervention(s)	Comparison group(s)	Screening tools(s)	Type of psychological intervention	Task shifted	Summary of findings
1.(Jiang et al. 2014) Cluster RCT China	Women within 4-6 weeks post-partum (Intervention group n=257 ; Control group n=514)	Mailing knowledge manuals on postpartum depression; Face-to-face counselling; Psychological counselling via telephone	Post-partum depressed women who were referred for further medical assistance	EPDS (>=10 screened positive)	Problem solving, aspects of cognitive techniques	Not specified	Decrease in postnatal depression especially with better maternal compliance
2.(Tripathy et al. 2010) Cluster RCT India	Women aged 15-49 years who had given birth during the study period (Intervention group n=6452 Control group n=5979)	Women participatory groups where they identify problems; come up with strategies to address the problem, implement them and assess the results Offered for 20 months	Enhanced care offered in health committee groups	Kessler-10 item scale (k10)	Aspects of problem solving	Yes Facilitator is a local woman trained to conduct the sessions	No significant effect in maternal depression initially, but a reduction in moderate depression in the third year Reduction in neonatal mortality
3.(Tezel & Gözüm 2006) A pre-test post-test mutual controlled experiment Turkey	Women who had a risk of post-partum depression but had no signs of major depression (Intervention group n=32 ; Control group n=30)	Women taught problem solving mainly and cognitive restructuring weekly during home visits for 6 weeks	Nursing care for depressive symptoms	EPDS (>11 screened positive	Problem solving Cognitive restructuring	No Offered by nurse researcher	Decrease in maternal depression in both nursing care and problem solving care but more so in nursing care (control).

Author, experimental design & location	Study participants	Description of intervention(s)	Comparison group(s)	Screening tools(s)	Type of psychological intervention	Task shifted	Summary of findings
4.(Rojas et al. 2007) Individual RCT Chile	Women with depression in their first postnatal year with index children less than 1 year old. (intervention group n= 114 ; control n=116)	Psycho-education as part of a multicomponent intervention. One session per week for 8 weeks (50mins) (pharmacotherapy if need be, systematic monitoring of progress, training of doctors and specialist supervision also included)	Usual care comprising mainly of medication and medical consultations rarely; psychotherapy and referral offered	EPDS (>=10 screened positive)	Problem solving, simple behaviour activation, cognitive techniques	Yes Midwives or nurses were trained for 8h and delivered the intervention with supervision.	EPDS score was lower in intervention arm than control arm at 3 months and 6 months. However the difference between these two groups decreased after 6 months.
5.(Rahman et al. 2008) Cluster RCT Pakistan	Married women in their third trimester with perinatal depression (Intervention n=463 ; control n=400)	Home visits from Community health care workers offering intervention that used cognitive behaviour techniques of active listening, collaboration with family and guided discovery 16 sessions	Enhanced usual care offered by untrained health worker with equal number of visits.	DSM-IV diagnosis then assessment using HDRS	Cognitive behaviour therapy, Problem solving, psycho-education, activating social networks	Yes Community health workers trained	Lower depression score for mother in the intervention arm as compared to control at both 6 months and 12months.
6. (Gao et al. 2012) Individual RCT China	First time mothers (Intervention group n=96 ; Control group n=98)	Routine antenatal care plus IPT-orientated childbirth education programmes.	Standard routine antenatal care	EPDS	Interpersonal therapy and psycho-education	Yes. Trained midwives offering the intervention	IPT oriented education programme provided skills and knowledge to help cope with the transition to motherhood which may enhance maternal role competence

Author, experimental design & location	Study participants	Description of intervention(s)	Comparison group(s)	Screening tools(s)	Type of psychological intervention	Task shifted	Summary of findings
7.(Baker-Henningham et al. 2005) Cluster RCT Jamaica	Mothers with undernourished children (Intervention n=76 ; control n=70)	Improving mothers knowledge and practices of child rearing through home visits plus nutrition care	Standard care and nutrition care	Centre for Epidemiologic Studies Depression Scale (CES-D)	Aspects of Psycho-education	Yes Community health workers trained	Psycho-education to improve undernourished children's development had significant effects in reducing maternal depression.
8.(Toth et al. 2013) Individual RCT	Mothers from a low-income urban area with a 12 month old baby (Intervention group n=99 ; Control group n=29)	IPT was offered according to a manual. Over a period of 14 sessions being offered for 1-hr on a weekly basis	Referral to services offered in the community	Centre for Epidemiologic Studies Depression Scale (CES-D) (>16 considered eligible) Beck Depression Inventory (>19)	Interpersonal Therapy	No	Decrease in depressive symptoms in the IPT group compared to the control.
9.(Aracena et al. 2009) Experimental RCT Chile	Adolescent mothers who conceived their first child between age of 14 and 19 years	Intervention included home visits with aspects of child health education, psycho-education and activation of social networks	Standard health care	General health questionnaire	Aspects of psycho-education, IPT	Yes. Community health workers	Women in the home visit group (intervention), show improved mental health as well as nutritional status. There is also an improved level of children's linguistic development compared to the control group

Author, experimental design & location	Study participants	Description of intervention(s)	Comparison group(s)	Screening tools(s)	Type of psychological intervention	Task shifted	Summary of findings
10.(Cooper et al. 2003) United Kingdom Individual RCT	English speaking first time mothers, living in close proximity to the hospital.	There were three intervention groups: CBT therapy, Psychodynamic therapy and non-directive counselling. Offered weekly from 8weeks to 18 weeks postpartum	Routine primary care offered by the health care team	EPDS (>12 screened positive for depression)	CBT, psychodynamic therapy	Yes. Non-specialists trained to offer the intervention and working under supervision of a specialist.	There was a decrease in maternal depression in all three intervention groups as compared to the control group at 4.5 months postpartum. At 9 months, 18 months and 5 years post-partum benefit of the interventions was no longer apparent (probably because of spontaneous remission)
11.(Milgrom et al. 2005) Australia Individual RCT	37-42 week pregnant women with depression.	There were three intervention groups : group-based CBT(n=46), group-based counselling (n=47), individual counselling (n=66)	Routine primary care (n=33)	EPDS (>12), then assessment using the Composite International Diagnostic Interview (CIDI)	CBT and aspects of problem solving in the counselling sessions.	No	Psychological interventions reduces maternal depressive symptoms more than routine care. Counselling may be as effective as CBT and these interventions can be maximised by being offered on a one to one basis.

Of the eleven studies reviewed above, seven used a task shifting approach to deliver the psychological intervention to the depressed mothers (Tripathy et al. 2010; Rojas et al. 2007; Rahman et al. 2008; Gao et al. 2012; Baker-Henningham et al. 2005; Ensor & Cooper 2004; Aracena et al. 2009). These findings suggest that task-shifting to trained non-health specialists, with appropriate supervision, can be of great benefit. These benefits include a larger population coverage, more efficient use of available health care staff and potentially higher acceptability to clients if the health workers are drawn from the local community and have some insight into the lived experience of their clients (Kagee et al. 2013).

Empirical evidence of economic evaluations of psychological interventions for maternal depression

An extensive search was conducted to find economic evaluation studies that focused on psychological interventions for maternal depression. Only five studies were found (Morell et al. 2009; Stevenson et al. 2010; Tripathy et al. 2010; Aracena et al. 2009; Bauer et al. 2014). This is indicative of the need for more economic evaluation research in this field. These studies are described in more detail in table 3 below.

Table 3: Summary of economic evaluation studies on psychological interventions for maternal depression

Study	Objective	Study participants & setting	Description of Intervention	Outcome measure(s)	Perspective taken	Range of costs	Summary of results	Conclusion
1 (Morell et al. 2009) Pragmatic randomised cluster trial	To investigate the outcomes of health visitors training on identifying postnatal depression and offering psychological interventions. To determine the cost-effectiveness of the intervention	Women 36 weeks pregnant during recruitment phase of the trial, gave birth to a live baby and consented to participate in the study	Women at 6 weeks postnatal period with an EPDS score >=12 were randomised into either the intervention group (IG) or control group (CG). The women in the IG could choose which of two interventions they preferred: CBT or person-centre approach (PCA) offered by the health visitors.	Proportion of women with an EPDS score of >12. For the economic evaluation; outcome was measured in QALYs gained	Societal Perspective	Costs of health visitors including training, baby immunisation costs, GP costs, prescription costs, costs of social worker, costs to the mother and baby and psychiatric admission costs	The two psychological interventions were cost-effective as compared to the control (lower mean costs and higher QALYs gained) CBT intervention was found to be most cost-effective.	No discounting was done as the costs incurred were within a period of one year.

Study	Objective	Study participants & setting	Description of Intervention	Outcome measure(s)	Perspective taken	Range of costs	Summary of results	Conclusion
2 (Stevenson et al. 2010) Meta-analysis	To evaluate the effectiveness and cost-effectiveness of group CBT compared with current care for women with postnatal depression.	Women in the postnatal period (up to 1year), scoring above cut-off point on EPDS or meeting criteria of diagnosis using DSM-IV. Studies from all settings were included. These studies were used to evaluate the clinical effectiveness of group CBT	All interventions that included aspects of cognitive behavioural principles in a group setting These studies were used to evaluate the clinical effectiveness of group CBT	Depression using EPDS and BDI For the economic evaluation; outcome was measured in QALYs gained	Provider perspective	Health visitor costs, costs of group facilitators (does not include set-up costs or additional running costs)	Group CBT was not cost-effective but after sensitivity analysis, there are scenarios where group CBT was found to be cost effective.	This was a meta-analysis however, no applicable literature was found for cost-effectiveness of group CBT, the authors therefore constructed an economic model

Study	Objective	Study participants & setting	Description of Intervention	Outcome measure(s)	Perspective taken	Range of costs	Summary of results	Conclusion
3 (Tripathy et al. 2010) Cluster RCT	To assess the effectiveness of women participatory groups on maternal depression.	Women aged 15-49 years who had given birth during the study period Setting is in India	Women participatory groups for a total of 20 monthly meetings. Through stories and games, group members identify maternal n new born problems, come up with strategies to address these problems, implement them, assess the results	Maternal depression scores and neo-natal mortality ratios For the economic evaluation; outcome measure was not specified	Providers perspective	Financial and economic costs of setting up the intervention and costs of running the intervention.	The women's participatory group was found to be cost-effective when compared with a do-nothing approach	Discount rate of 3% was used. No sensitivity analysis was mentioned

Study	Objective	Study participants & setting	Description of Intervention	Outcome measure(s)	Perspective taken	Range of costs	Summary of results	Conclusion
4 (Aracena et al. 2009) Experimental RCT	To determine effectiveness and cost-effectiveness of home visits on mothers mental and physical health as well as childrens linguistic development	Adolescent mothers who conceived their first child between age of 14 and 19 years	Intervention included home visits with aspects of child health education, psycho-education and activation of social networks	Primary outcome; physical health of mother and baby Secondary outcome; mental health of mother using the general health questionnaire For economic evaluation; outcome measure not specified (refers to unit of effectiveness)	Providers perspective	Health care costs, administrative and logistic costs	Home visits associated with higher costs and higher outcomes compared to the standard of care. (implementation depends on how much value policy makers place on the outcomes)	No discounting or sensitivity analysis was mentioned

Study	Objective	Study participants & setting	Description of Intervention	Outcome measure(s)	Perspective taken	Range of costs	Summary of results	Conclusion
5 (Bauer et al. 2014) Cost analysis	To determine the costs and social impact of maternal mental health problems in the perinatal period (Perinatal period was defined as the period during pregnancy and the first year after birth)	This study used secondary data of published literature, combined data sets and extrapolated data where necessary Setting is in the United Kingdom (UK)	It was a cost analysis of the impact of maternal mental health problems in the perinatal period and no intervention was offered in this study	There was no outcome measure	Public sector perspective and societal perspective	Costs of health service use, Productivity losses costs and losses of quality adjusted life years (QALYS)	Maternal mental illness costs an equivalent of just under £10,000 for every single birth in the UK. 72% of these costs relates to the adverse impact on the the child rather than the mother 1/5 of the total costs (£1.7billion) are borne by the public sector	Dicounting of costs after the first year was done at a rate of 3.5%

Three of the studies were trials; pragmatic cluster randomised trial (Morell et al. 2009); experimental RCT (Aracena et al. 2009) and cluster randomised trial (Tripathy et al. 2010). The fourth study was a meta-analysis, however, because no literature was found for the cost-effectiveness of group CBT, which was the focus of the study, an economic model was constructed to determine the cost effectiveness of group CBT (Stevenson et al. 2010). The fifth study was a cost analysis (Bauer et al. 2014).

One out of the five economic evaluations that was reviewed was a cost analysis study, as mentioned above and therefore an outcome measure was not included in this study (Bauer et al. 2014). The other four economic evaluations that were reviewed were all classified as cost-effectiveness studies by the authors. Having said that, Stevenson et al. (2010) and Morell et al. (2009) used QALYs gained as the outcome measure while the outcome measures in the other two studies were in natural units such as reduction in maternal depression scores (Tripathy et al. 2010) and the mental health of the mother as well as the development in child's language skill (Aracena et al. 2009).

In two of the studies, psychological interventions for postnatal depression were argued to be cost-effective (Morell et al. 2009; Tripathy et al. 2010) based on incremental cost-effective ratios (ICERs) that were below the National Institute for health and clinical excellence (NICE) threshold (Morell et al. 2009). The interventions employed in these studies included CBT and women participatory groups using aspects of problem-solving. On the other hand, another study developed an economic model for analysis and found that group CBT was not cost-effective at base case based on ICERs against the NICE threshold (Stevenson et al. 2010). The fourth study did not explicitly mention whether the home visit intervention (with aspects of psycho-education and IPT) was cost-effective or not (Aracena et al. 2009). Instead, Aracena et al. (2009) show that the intervention has higher costs and higher benefits than standard care and that implementation of the intervention would depend on how much value the policy maker places on the outcome, which in this case is improved mental and physical health of the mother, amongst others. The cost analysis study indicates that the costs of maternal mental illness in the perinatal period is just under £10,000 for every single birth in the UK. The study further reports that most of

these costs (72%) relate to the child other than the mother and that a 1/5 of the total costs are borne by the public sector (Bauer et al. 2014).

Three of the studies employed the health care provider's perspective (Stevenson et al. 2010; Tripathy et al. 2010; Aracena et al. 2009), one employed the broader societal perspective (Morell et al. 2009) while the other one employed both the provider and societal perspective (Bauer et al. 2014). Most studies adopt the provider's perspective as they tend to focus on the relevant costs incurred by the people commissioning the study (Drummond et al. 2008). While the broader societal perspective is normally recommended in the literature, Drummond et al. (2005) argue that the inclusion of patient costs which are often lower than provider costs may not alter an implementation decision. All the five studies explore the different costs that are included and this is illustrated in Table 3 above. However, one of the studies is exclusively a cost analysis and therefore an extensive look of the different societal costs are discussed (Bauer et al. 2014). These costs include: costs of health care service use that were obtained using the national unit costs from an annual compendium; productivity losses costs that were derived using mean weekly wage rates for full time and part time employees; and losses of QALYs using willingness to pay as well as thresholds from the NICE guidelines (Bauer et al. 2014). The calculations in this cost analysis study took account of the data on prevalence and the course of mental health conditions.

Uncertainties in economic evaluations arise because of four possible reasons: data requirements of the study, the need to extrapolate data over time, desire to generalize results and the choice of analytical tools (Briggs 1995). As a result of these uncertainties, sensitivity analyses are important to test the robustness of the study results (Briggs 1995). Only two of the four economic evaluations in this review conducted sensitivity analysis (Stevenson et al. 2010; Morell et al. 2009). For example, Stevenson et al. (2010) created a variety of scenarios to explore possible cost-effectiveness findings.

Discounting in economic evaluations is of importance, as a result of 'positive time preference' (Drummond et al. 2005). This means that people are not indifferent to time and would rather enjoy benefits now and postpone the costs incurred to the future, therefore the value that people attach to costs and benefits reduces with time

(Morris et al. 2007). The choice of the discount rate affects the magnitude of costs in economic evaluations, with larger discount rates giving less weight to the future events and vice versa (Morris et al. 2007). There is no specific discount rate that can be used in all economic evaluations, but rather the rate chosen should be consistent with economic theory, align with any government recommended rates or should facilitate comparison to other published studies (Morris et al. 2007). In the studies reviewed in this section, one study used a discount rate of 3% for costs (Tripathy et al. 2010), another used a discount rate of 3.5% (Bauer et al. 2014). Two of the studies did not discount any of the costs or the outcomes, which was appropriate given that the timeframe of the analysis was restricted to a one year period (Stevenson et al. 2010; Morell et al. 2009) while the third did not mention discounting specifically (Aracena et al. 2009) .

All four cost-effectiveness studies used ICERs to judge cost-effectiveness (Morell et al. 2009; Stevenson et al. 2010; Tripathy et al. 2010; Aracena et al. 2009). Two of the studies evaluated the ICERs against the National Institute for Health and Clinical Excellence (NICE) threshold (Morell et al. 2009; Stevenson et al. 2010) while the other studies did not explicitly mention a threshold.

Summary and Conclusion

Maternal depression can negatively affect both the mother and infant, and if untreated, high health care costs may be incurred for these women and their children. A review of literature suggests that there are different types of psychological interventions that can be offered to these mothers in a manner that is feasible and can be effective in reducing maternal depressive symptoms. Different screening methods were used in these studies and the interventions were offered for a duration that ranged from a period of 6 weeks to 20 months. From the studies, the longer the psychological intervention was offered, the longer the effects would last.

Very few published economic evaluations of psychological interventions for maternal depression were identified. The main gap that was identified was the need for more economic evaluations, be it partial or full analyses, to be conducted for psychological interventions for maternal depression. In addition, there were very

few studies on the economic burden of maternal depression in low and middle income countries. This is another gap that this study hopes to address.

In conclusion as much as the effectiveness of psychological interventions has been established in this review, this study hopes to contribute to the literature through establishing the health utilisation costs of untreated maternal depression in Khayelitsha, South Africa and to estimate the costs of offering a psychological intervention to depressed mothers.

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PART C: JOURNAL MANUSCRIPT

Proposed journal: Cost Effectiveness and Resource Allocation[1]

[1] The journal instruction for authors is included as appendix 5. For the purpose of this thesis, the student is the sole author. Tables and figures have been included in the text instead of at the end of the manuscript, to improve readability. Author's contribution and information was left out for this thesis.

MATERNAL DEPRESSION IN KHAYELITSHA, SOUTH AFRICA: A COMPARISON OF THE HEALTH UTILISATION COSTS OF MATERNAL DEPRESSION AND THE COST OF INTERVENING THROUGH A TASK-SHIFTED PSYCHOLOGICAL INTERVENTION.

Abstract

Background: Maternal depression is more prevalent in low and middle income countries. In South Africa, the reported high prevalence rates could be as a result of the HIV epidemic, violence, unwanted pregnancies, poverty, partner conflict and a lack of social support. If maternal depression is left untreated it leads to negative obstetric outcomes, negative impacts on the infant, economic losses and possibly suicide. Despite the major effects that maternal depression results in, it is not receiving the attention it deserves in South Africa. The aims of this study are to (1) determine the health service utilisation costs of untreated maternal depression as well as (2) the costs of offering support to these women through a task-shifted psychological intervention.

Methods: The costs of maternal depression were established within a population of pregnant women with different severity levels of depression presenting for their first antenatal visit in two different settings. Patient exit interviews were used to establish the utilisation of a range of health care services that were combined with average unit costs to establish provider costs. In a similar way, patient indirect and direct non health care costs were established. Health service utilisation costs of maternal depression were obtained and adjusted p-values were derived by controlling for mother's depression status, age, education, income and employment status. Using a provider's perspective, the costs of a psychological intervention to support depressed mothers was estimated, and compared to "enhanced usual care". The intervention included 6 counselling sessions delivered by community health workers while enhanced usual care included one phone call per month for 3 months, again delivered by community health workers.

Results: At the time of patient exit interview, the average length of pregnancy was 4 months. During the 3-month period preceding the interview, women with no depression used an average of 0.33 clinic visits in comparison to 0.43 and 0.71 clinic visits for women with mild depression and moderate/severe depression respectively ($p=0.002$). The length of hospital admissions was 1.6 times longer for women with moderate/severe depression in comparison to those with mild depression. The public sector total cost per

mother/child pair for 3 months was $120.86 for women with moderate/severe depression, $73.17 and $18.73 per mother/child pair with mild depression and no depression respectively (p=0.000). The cost per mother was $230.47 for the intervention and $69.93 for enhanced usual care. Cost per counselling visit was $33.96 while the cost per telephone call in enhanced usual care was $14.42.

Conclusion: Women with maternal depression incur significantly higher health care costs than those without. Support to these mothers can be offered and according to this study, it would cost $230.47 per mother. Affordability would be dependent on the budget constraint.

Keywords: Maternal depression; psychological intervention; task-shifting; health-care utilisation; cost-analysis.

Background

Maternal depression is a mental health condition that is a huge public health problem that can affect women during pregnancy or in the first 12 months postpartum [1]. Studies have shown that maternal depression and other maternal mental disorders are nearly three times more prevalent in low and middle income countries as compared to high income countries [2]. In South Africa, high prevalence rates have been reported with isolated studies estimating postnatal depression prevalence rates of 16.4% in Soweto [3] and 39% in an informal settlement in Cape Town [4]. In rural KwaZulu-Natal, an area with high human immunodeficiency virus (HIV) prevalence, the prevalence of prenatal depression was estimated at 47% [5]. The high prevalence rates of maternal depression in South Africa can be associated with factors such as the HIV/AIDS (Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome) epidemic, poverty, unwanted pregnancies, violence, infidelity, partner conflict and lack of social support [6, 7].

Maternal depression can be incapacitating to the mother leading to negative obstetric outcomes such as preterm labour, poor physical health, pregnancy complications and possibly suicide (World Health Organization 2008). These effects can be far reaching, affecting the productivity of the woman at work leading to economic losses, as well as negatively affecting the growth and behaviour of the infant [9]. As a result of these consequences of maternal depression, studies provide evidence that women with maternal depression tend to use more health care services either for themselves or for their children [10, 11]; which leads to higher health care costs [12]. This increase in health care costs could be as a result of delayed health seeking behaviour which may result in longer and more intense care once services have been accessed [13].

It is therefore of importance to provide support to women with maternal depression to ameliorate the increased health care costs as well as improve their quality of life. Currently in South Africa, antenatal services include three visits and cover approximately 92% of pregnant women with the main focus being the physical health of the mother [2]. After delivery, the focus does not shift to the emotional health of the mother but rather it shifts to the infant. This suggests that maternal depression is overlooked and underdiagnosed because of the lack of integration of maternal mental health into antenatal services at the primary care level [14].

The WHO Mental Health Gap Action Programme (mhGAP) has produced guidelines for the treatment of prenatal and postnatal depression [15]. For moderate and severe depression, prescription medication is recommended. However, many women may be sceptical about taking medications during pregnancy or while breast feeding making adherence and acceptability quite low. In addition, these women would need extra support from their psychiatrists when on these medications [16]. It could therefore be more appropriate to use psychological approaches, which may be more acceptable to women [16]. Psychological interventions are generally defined as methods that induce a change in a person's thinking or behaviour through utilising strategies such as goal-setting, visualization, relaxation and other common techniques [17].

Psychological interventions are a novel approach in addressing maternal depression; however a shortage of mental health workers limits implementation. The lack of resources is evidenced by a scarcity of psychiatrists and psychologists available to serve the population [18]. In addition, there is a limited budget allocated to mental health: South Africa's mental health expenditure by the government is unknown [18]; it is however reported that most African countries spend less than 1% of total health budget on mental health [19]. In order to help tackle the problem of work overload that is brought about by scarce human resources, a task shifting approach has been recommended by the World Health Organisation and others [20, 21]. Task shifting involves the use of non-specialist health workers to perform a task usually allocated to a specialist [22]. Typically, the workers that are given the new task to perform have lower qualifications and receive specific training and ongoing supervision focused on the particular task [22]. In this study, community health workers (CHWs) implemented the psychological intervention which included aspects of psycho-education, problem-solving therapy, behavioural activation, cognitive reframing and relaxation training. While literature has demonstrated the effectiveness of these interventions for the treatment of maternal depression [23–28], few economic evaluations have been conducted especially in low and middle income settings [29–32].

Given this background, the aims of this study are to: (1) determine the health service utilisation costs of untreated maternal depression; and (2) estimate the provider costs of offering support to these women through a task-shifted psychological intervention.

Methods

Study design

In order to provide needed information about the burden of maternal depression on the health system and communities, this study enrolled women from two antenatal services who showed signs of psychological distress. Through the use of the Hamilton Depression Rating Scale (HDRS), the health care utilisation costs among participants was compared depending on the severity of depression: no depression (score0-7), mild depression (score 8-16) and moderate/severe depression (score ≥17) [33]. In doing so the study aims to provide estimates of the health service utilisation costs of untreated maternal depression. Subsequent to reporting the finding of the cost of untreated depression, this study aims to inform policy makers about the costs of supporting these women through a task shifted psychological intervention.

The health care costs associated with maternal depression were analysed from both the provider and patient perspective using a gross costing approach. These costs were compared among psychologically distressed pregnant women without depression, those with mild depression and those with moderate/severe depression. This analysis was done on data that was collected using patient exit questionnaires during the first antenatal visit, where the participants were on average 4 months pregnant.

Costing of the task-shifted psychological intervention and enhanced usual care was done using a micro-costing approach. All costs were expressed in 2014/15 prices and converted to United States Dollars (1US$= 11.69 South African Rand (ZAR) using an average exchange rate over the same period [34].

Study population and setting

The study population included participants of the Africa Focus on Intervention Research for Mental Health (AFFIRM) study. The participants were women 18 years and older who screened positive for depression using the Edinburgh Postnatal Depression Scale (EPDS) at their first antenatal clinic visit, which is normally in the second trimester, and who consented to be part of the study [35] .

The two sites where women were recruited were the midwife obstetric units of Site B Community Health Centre and Michael Mapongwana Community Health Centre, both in Khayelitsha. Khayelitsha is a settlement found on the outskirts of Cape Town [36]. This peri-urban settlement has about 500,000 inhabitants many of whom live in shacks without running water or electricity [37]. The area is characterised by high rates of unemployment, crime and violence [37].

Screening and Recruitment

Recruitment and screening was done by the AFFIRM study [35]. Potential participants were recruited from the Midwife Obstetric Units of Site B Community Health Centre and Michael Mapongwana Community Health Centre in Khayelitsha. Only women who gave verbal consent were eligible for screening for depression. Screening was done by trained field workers in collaboration with nurses conducting the antenatal assessments to ensure that all potential participants attending the clinics were screened. Women who gave informed consent were recruited through a three stage screening process:

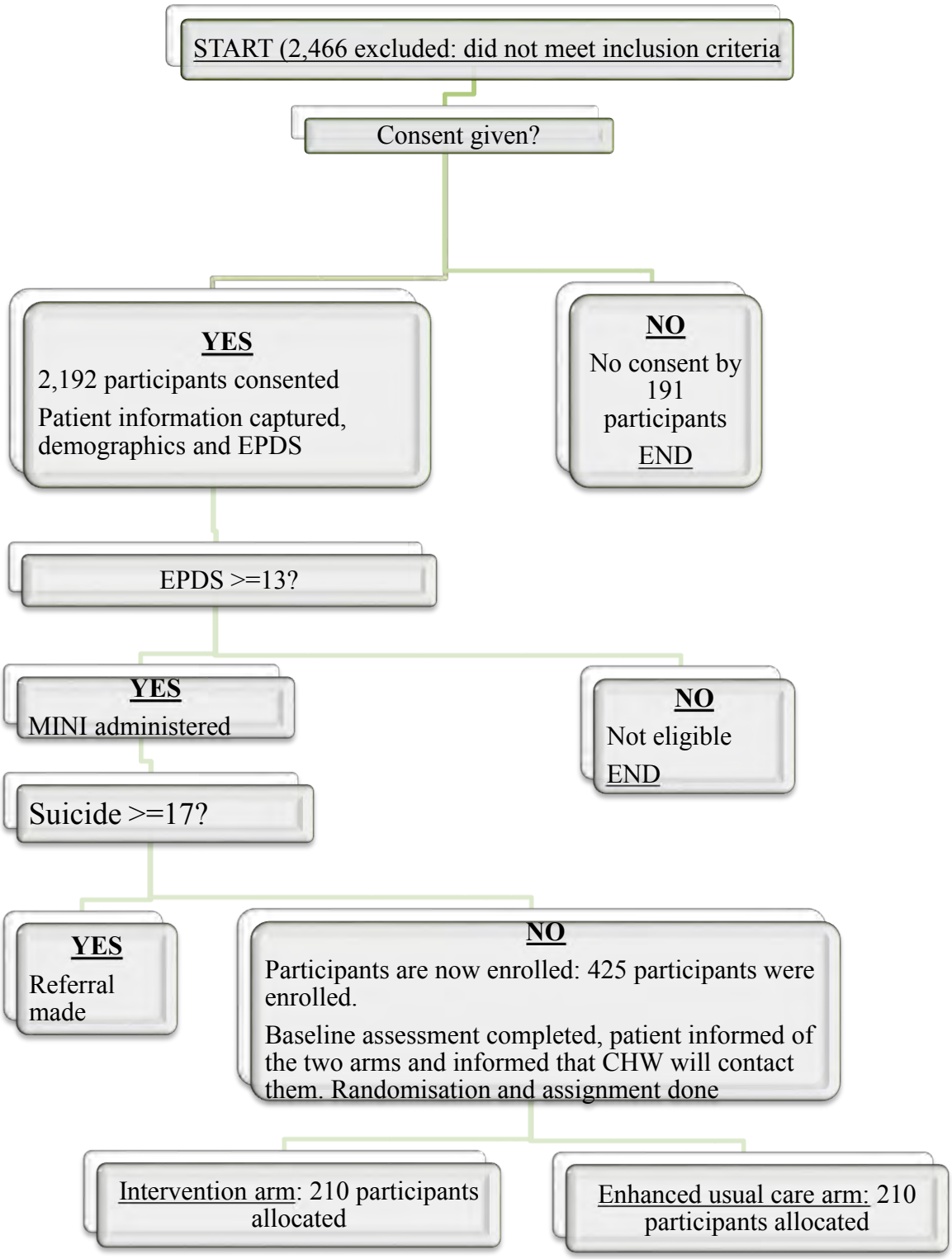
- Verbal confirmation of eligibility into the study
- Completion of demographic questions
- Administration of the EPDS

Following the screening process outlined above, those who scored 13 and above in the EPDS were recruited into the study, and were asked to complete a full baseline interview with the field worker. These participants were also screened for signs of suicidality. Any participant who scored 17 or higher on the MINI scale was referred to the nursing sisters at the clinics for further assessment and possible referral to Khayelitsha District Hospital. After referral, if the health care practitioner deemed it fit, these participants were maintained in the study together with those with low MINI scores.

In total, 2192 participants were screened for depression out of which 425 participants screened positive and 420 were recruited into the study. 210 participants were allocated to each of the intervention and control arm using a computerised data management system. This is illustrated in figure 1 below.

Figure 1: Recruitment and screening

Source: Adapted from AFFIRM study [35]



Description of the intervention

A full description of the intervention is available from published sources [35]. In brief, twelve CHWs from a local non-governmental organization were trained to deliver the manual-based counselling intervention. Intervention design, including aspects of psycho-education, cognitive reframing, behavioural activation, problem-solving therapy and relaxation therapy, was informed by a review of available literature and research that was conducted for 12 months preceding the trial. The training was for a period of 5 days, and was facilitated by the mental health counsellor, who is a trained clinical social worker. Based on their motivation, understanding of the course material and observed counselling skills demonstrated through mock counselling sessions, six of the twelve CHWs were selected.

Participants randomized to the intervention arm received the psychological treatment delivered by the trained CHWs. They received six counselling sessions each of approximately 1 hour duration. Counselling sessions were scheduled to align as closely as possible with routine antenatal check-ups, and were delivered approximately every two weeks. However, if the mother was enrolled late in her pregnancy, the counselling sessions continued into the postnatal period until all 6 sessions were done. Follow-up was done by the CHWs to mothers with depression in the intervention arm who missed any sessions; this was mainly done through phone calls. A drop out was defined as any woman who missed three consecutive counselling sessions.

Fidelity checks were important for determining whether the CHWs were delivering the intervention as it was intended. The following measures were put in place to assess fidelity:

- CHWs would complete a checklist after each session, indicating what was covered during that session
- Mental health specialist would observe the initial sessions and discuss them with the CHWs
- Group supervision sessions were done to revise CHW's knowledge
- All counselling sessions were recorded and mental health counsellors would listen to them; initially all but later, at random

Description of the control

Four independent CHWs were trained by the mental health specialist for two days on how to conduct the phone calls to the depressed mothers in the control arm – to be done on a monthly basis over three months. They were trained on how to identify any suicide ideation and refer the mothers to psychiatric nurses if needed. At the end of the training, two CHWs were selected to deliver the phone calls; their training excluded the counselling techniques that were used in the intervention arm.

This control arm entailed enhanced usual care. Usual care during antenatal and postnatal check-ups involves foetal and infant physical development and immunization. Enhanced usual care therefore included usual care and in addition, regular monthly phone calls over a period of 3 months delivered by the two CHWs. It was important that a balance was achieved between the number of phone calls that was needed to monitor any adverse changes in the woman's mood versus being too intrusive and not reflecting usual care. The final decision of 3 phone calls was informed by research, discussion among the research team and aligning with the timing of the psychological intervention. The telephone calls by the CHWs entailed engaging the participants on a brief conversation regarding the following:

- General questions about how the woman was feeling
- Questions about changes in the woman's life (if any, one would enquire what they were)
- Questions about whether there was anyone to assist her if she needed help
- Questions about whether she was visited by any other CHWs from other organizations and the nature of the visits
- Questions to gauge suicide ideation

Fidelity checks in this arm were also employed. The CHWs were required to fill out a checklist regarding the information covered during the phone call, any referrals made or any adverse events. The mental health counsellor would also monitor the calls delivered by the CHWs at random.

Data collection: health utilisation costs of maternal depression

Patients were interviewed by fieldworkers and patient responses were entered into a mobile device that was linked to Mobenzi Researcher. Field workers followed the instructions on Mobenzi Researcher which would handle the skip logic, synchronization and repeat rules automatically [38].

The questionnaire consisted of several sections, however the sections that were relevant in this analysis were: demographics, HDRS and health care utilisation. Demographics included age and socioeconomic characteristics of the patient such as education and employment status. The HDRS was important in classifying the participants according to the severity of depression as having no depression, mild depression or moderate/severe depression. The health care utilisation questionnaire allowed an estimation of the number of inpatient days, and a range of ambulatory visits including hospital outpatient departments and primary health care clinics. These estimates were combined with average unit costs, obtained from provincial figures, to obtain provider costs. On the other hand, information on the patient travel time, waiting time at the hospital, consultation time, travel costs and out of pocket payments were also collected and are used in the calculation of patient costs. The patient's time that was used when seeking healthcare services was monitized Following the literature, the opportunity cost of time lost from productive activities can be valued using wages/salary earnings foregone [39]. In this study, the average income across the group was used as a proxy of this opportunity cost.

Data analysis: health utilisation costs of maternal depression

Analysis was done using STATA 13.0. From the provider perspective, we obtained the cost of utilising a range of health care services, per mother/child pair, during the period of early antenatal care. To enable meaningful analysis, these costs were calculated to represent a three month time frame, and were compared among pregnant women without depression, those with mild depression and those with moderate/severe depression. Participants reported health care utilisation patterns over a period of 6 and 3 months for hospital admissions and outpatient visits respectively prior to the first antenatal visit. In light of the fact that the first antenatal visit is done during

the first 12 weeks of pregnancy, a three month time frame was deemed appropriate to represent health care costs of participants during their early to mid-pregnancy phase.

This was achieved by determining both the unit costs of inpatient days and outpatient visits and multiplying by the number of days or visits determined from the patient survey. The Western Cape Department of health annual report 2014/15 was the main source of these unit costs [40]. For hospital admissions and hospital outpatient visits, because the level of government hospital was not specified by the patient, a weighted US dollar/patient day equivalent (US$/PDE) was calculated with the weighting derived using the proportion of PDE at each level of care within the province. For primary health care visits, the weighted cost per outpatient department and expenditure per primary health care visit was used to derive the costs [40]. Given that private sector services are normally charged on a fee-for-service basis, the mother's reported out of pocket payments were used as a proxy for the costs spent on private services . From the patient perspective, out of pocket expenditures, travel costs and opportunity costs were analysed. An incremental cost for health care utilisation between women who have moderate or severe depression and those with no depression was derived from both the provider and patient perspective.

In the analysis, p-values were derived using the Kruskal-Wallis comparison of means test for quantitative data while the Pearson's chi-squared test was used for the categorical data. In addition to the un-adjusted p-values, adjusted p-values were also derived for health care costs. These adjusted p-values were derived by running a Poisson regression model and controlling for variables such as mother's depression status, age, education, income and employment status. The Poisson model was deemed appropriate because it is used for modelling count data [41].

Data collection and analysis: intervention costs

Costs

Costs were analysed from a provider's perspective and included both recurrent and capital costs. For easier analysis, costs were grouped into screening costs, start-up costs, cost of the rooms and recurrent costs. This

applied to both the enhanced usual care and intervention arms. Provider costs were obtained from the project manager of the AFFIRM study as well as from market prices. The costs were reported based on the 2014/2015 financial year prices and salaries.

All the costs were calculated and reported in US$ (1US$= 11.69 South African Rand (ZAR)) as mentioned above. An average cost per patient screened positive was obtained by estimating the total screening costs divided by the number of women screened positive. In addition, the cost of offering the intervention per client as well as the cost per counselling visit was obtained. This was replicated for the enhanced usual care. The time period for all these costs was from the beginning of the AFFIRM study to when offering of the intervention was completed, a period of one year and eight months.

Costs of screening

These costs included the costs required to train the field workers, the costs of the fieldworkers (who were the screeners), the costs of any stationary used and the share of the capital cost of the building that was used for screening.

Start-up costs

These costs included any non-recurrent costs that were incurred at the beginning of the trial. These included development of the training manuals, training and purchasing of equipment. The developing of the training manual involved the mental health counsellor spending time researching relevant literature and coming up with a manual that would be used as a guide for the psychological intervention. This was developed over a period of 5 months prior to the implementation of the intervention. Training costs were also incurred through paying the mental health counsellor to offer the training. Equipment that was used in the intervention included tables, chairs, voice recorders for fidelity checks, training manuals, cell phones given to the CHWs, telephones and a relaxation compact disc (CD). These start-up costs were considered as capital costs as they are assets that are used over a period of time [42]. Therefore the equipment was allocated 5 useful life years with the exception of cell phones and the training manual that were allocated 3 useful life years. Training itself was also allocated 3

useful life years. These start-up costs were annualised using an 8% interest rate, based on the long term return on government bonds in South Africa [43].

Cost of rooms

In Michael Mapongwana Community Health Centre, three rooms were used to offer the intervention while in Site B Community Health Centre, two rooms were used. The sizes of these rooms were measured and a cost was allocated to the rooms based on the building cost per square metre in South Africa [44]. It was assumed that buildings had a useful life of 30 years. These costs were annuitized using the same 8% interest rate [43].

Recurrent costs

Recurrent costs were those costs that were repeatedly incurred throughout the intervention. Human resource costs, as well as costs for items such as airtime, data bundles, transport costs, telephone costs, and food costs were all included in recurrent costs. Human resource costs were obtained by estimating a percentage time spent on relevant activities and using monthly salaries to estimate salary costs for the mental health counsellor as well as the CHWs. In addition, items that would last for more than one year such as kettles and heaters but cost less than US$100 were considered as recurrent costs [45].

Sensitivity analysis

In this study 19% of participants screened positive. This proportion was increased to see what the costs would be in the event of a higher or lower prevalence of depression. The interest rate in which the capital costs were annuitized was also varied to determine whether or not this had a significant impact on the costs. The main cost drivers were also varied to determine if these had a major impact on study results. All these were done to determine the robustness of the study's results.

Ethical approval

The AFFIRM study obtained ethical approval from the University of Cape Town Human Research Ethics Committee (Ref no 226/2011) and the National Institute of Mental Health (NIMH) prior to the recruitment of

participants. This study also obtained ethical approval from the University of Cape Town Human Research Ethics Committee (Ref no 469/2015).

Results

Respondent characteristics

Despite the enrolment of 425 women into the study, field workers managed to record the characteristics of 419 participants, hence six participants were excluded from the study. Of the included participants,15 (4%) had no depression, 233 (56%) had mild depression while 170 (40%) had moderate/severe depression according to the HDRS.

The women in this study ranged from 18-45 years, with an average age of 28 years. The women had an average of 2 pregnancies (p=0.151), with a majority having 1 live birth. The participants had attained some level of education, with 73%, 86% and 80% of those without depression, those with mild depression and those with moderate/severe depression respectively having attained further education according to the South African system. 47% (n=7) of the women without depression were unemployed, 42% (n=99) of the women with mild depression were also unemployed, while 38% (n=65) of the women with moderate/severe depression were in unemployment. Majority of the women had a partner but did not live with the partner: 67% (n=10) for those without depression, 63% for those with mild depression and 65% for those with moderate or severe depression. . The above shows that participants across the different severity levels of depression had relatively similar baseline characteristics. This is illustrated in Table 1 below.

Table 1: Socio-demographic characteristics of the participants in the study

	No depression (n=15)	Mild depression (n=233)	Moderate/Severe depression (n=170)	p-value
Mean age in years (median)	29.80 (30)	27.07 (27)	27.34 (27)	0.301
Mean number of pregnancies	2.27	2.15	2.45	0.151
Mean gestation period in weeks (months)	14.33 (3.58 months)	16.53 (4.13months)	17.35 (4.34 months)	0.077
Number of live births (%)				
0 live births	4 (27%)	82 (35%)	52 (31%)	0.211
1 live births	7 (47%)	96 (41%)	64 (38%)	
2 live births	3 (20%)	39 (17%)	34 (20%)	
3 live births	1(7%)	12 (5%)	11 (7%)	
4 live births	0 (0%)	4 (2%)	7 (4%)	
5 live births	0 (0%)	0 (0%)	2 (2%)	
Education status*** (%)				
Reception to grade 3	0 (0%)	1 (0.4%)	2 (1%)	0.704
Grade 4-6	0 (0%)	1 (0.4%)	0 (0%)	
Grade 7-9	3 (20%)	20 (9%)	21 (12%)	
Grade 10-12	11 (73%)	200 (86%)	136 (80%)	
Tertiary education	1 (7%)	11 (5%)	11 (7%)	
Employment status (%)				
Formal employment (full/part time)	5 (33%)	86 (37%)	56 (33%)	0.385
Casual jobs	2 (13%)	9 (4%)	9 (5%)	
Self-employed	1 (7%)	10 (4%)	12 (7%)	
Unemployed	7 (47%)	99 (42%)	65 (38%)	
Still studying	0 (0%)	29 (13%)	28 (17%)	
Relationship status (%)				
Has partner and live together	5 (33%)	81 (35%)	57 (34%)	0.249
Has partner but don't live together	10 (67%)	146 (63%)	111 (65%)	
No partner and lives with family	0 (0%)	6 (3%)	0 (0%)	
No partner and lives alone	0 (0%)	0 (0%)	2 (1%)	

Health care service use

The unit costs of various services were used to derive the cost of depression and are illustrated in table 2 bel

Table 2: Unit costs of services
(Source: Western Cape Department of Health Annual Report 2014/2015)

Hospital inpatient and outpatient visit			
	Cost per inpatient day	Cost per hospital outpatient visit	PDE
District hospital	$157.26	$51.61	1,366,684
Provincial hospital	$226.23	$72.93	564,442
Central hospital	$366.50	$121.08	1,009,499
Average weighted cost per inpatient day = $242.33			
Average weighted cost per hospital outpatient visit = $79.55			
	Primary health care		
Cost per visit	$56.20		

The number of outpatient visits and inpatient days increased as the severity of depression increased among the women. For outpatient visits, most of the women would go to clinics, followed by additional private services and hospital outpatient visits would be the least likely among all the participants. The average number of clinic visits in 3 months for those with moderate/severe depression was 0.71 visits, 0.43 visits for those with mild depression versus 0.33 visits for those without depression (p=0.002). The length of hospital admission was 1.6 times longer among those with moderate/severe depression in comparison to those with mild depression (p=0.000). Over the 3 month period, public sector outpatient costs (including all ambulatory services) increased as severity of depression increased: $18.73 per mother/child for those without depression, $24.80 per mother/child for those with mild depression and $43.88 per mother/child for those with moderate/severe depression (p=0.000). On average, the total public sector cost per mother/child over the 3 month period was $120.86 for women with moderate/severe depression, $73.17 per mother/child for those with mild depression as compared to $18.73 per mother/child for those without depression (p=0.000): a mean cost difference of $102.13 between those with moderate/severe depression and those with no depression. This is illustrated on table 3 below.

Table 3: Health service utilisation and provider costs of maternal depression

	No depression (n=15)	Mild depression (n=233)	Moderate/Severe depression (n=170)	Un-adjusted p-value	Adjusted p-value
Clinic visits (3 months)					
Average number of clinic visits per mother/child	0.33	0.43	0.71	0.001	0.002
Average cost for clinic visits per mother/child	$18.73	$24.12	$39.67	0.001	0.000
Hospital outpatient visits (3 months)					
Average number of hospital outpatient visits per mother/child	0.00	0.01	0.05	0.132	0.570
Average cost for hospital outpatient visits per mother/child	$0.00	$0.68	$4.21	0.132	-
Private services (3 months)					
Average number of private service visits per mother/child	0.07	0.10	0.18	0.228	0.138
Average cost for additional private services per mother/child	$1.06	$1.63	$2.79	0.228	0.000
Hospital admissions (3 months)					
Average number of inpatient days days per mother/child	0.00	0.20	0.32	0.260	0.000
Average cost for hospital admissions per mother/child	$0.00	$48.36	$76.98	0.260	0.000
Totals					
Average public sector outpatient cost per mother/child	$18.73	$24.80	$43.88	0.000	0.000
Average public sector cost per mother/child	$18.73	$73.17	$120.86	0.000	0.000

From a patient perspective, women with moderate/severe depression reported that they spent 2.71 more hours off from work in order to seek medical attention during this 3 month period than those with no depression. The average out of pocket payments and travel costs for mothers without depression were: $0.00 and $0.44 versus $3.37 and $1.07 for those with moderate/severe depression (p=0.000 and 0.001 respectively). In total the patient costs in 3 months amounted to $0.97, $3.61 and $7.41 for those with no depression, those with mild depression and those with moderate/severe depression respectively (p=0.000) : an incremental difference of $6.44. between the first and last groups. This is illustrated on table 4 below. Therefore the health service utilisation costs of maternal depression are $128.27 for those with moderate/severe depression, $76.78 for those with mild depression and $19.70 for those with no depression over this same 3 month period.

Table 4: Costs incurred by pregnant women, per 3 month period

	No depression (n=15)	Mild depression (n=233)	Moderate/Severe depression (n=170)	Un-adjusted p-value	Adjusted p-value
Time off work					
Average time off work (hours)	0.84	2.89	3.55	0.000	0.000
Average opportunity cost	$0.53	$1.83	$2.97	0.000	0.000
Out of pocket payments (OOPPs)					
Average outpatient OOPPs	$0.00	$1.31	$3.28	0.014	0.000
Average inpatient OOPPs	$0.00	$0.01	$0.09	0.131	0.000
Average total OOPPs	$0.00	$1.32	$3.37	0.005	0.000
Travel cost					
Average total travel cost	$0.44	$0.46	$1.07	0.001	-
Average cost incurred per mother	$0.97	$3.61	$7.41	0.000	0.000

Intervention costs

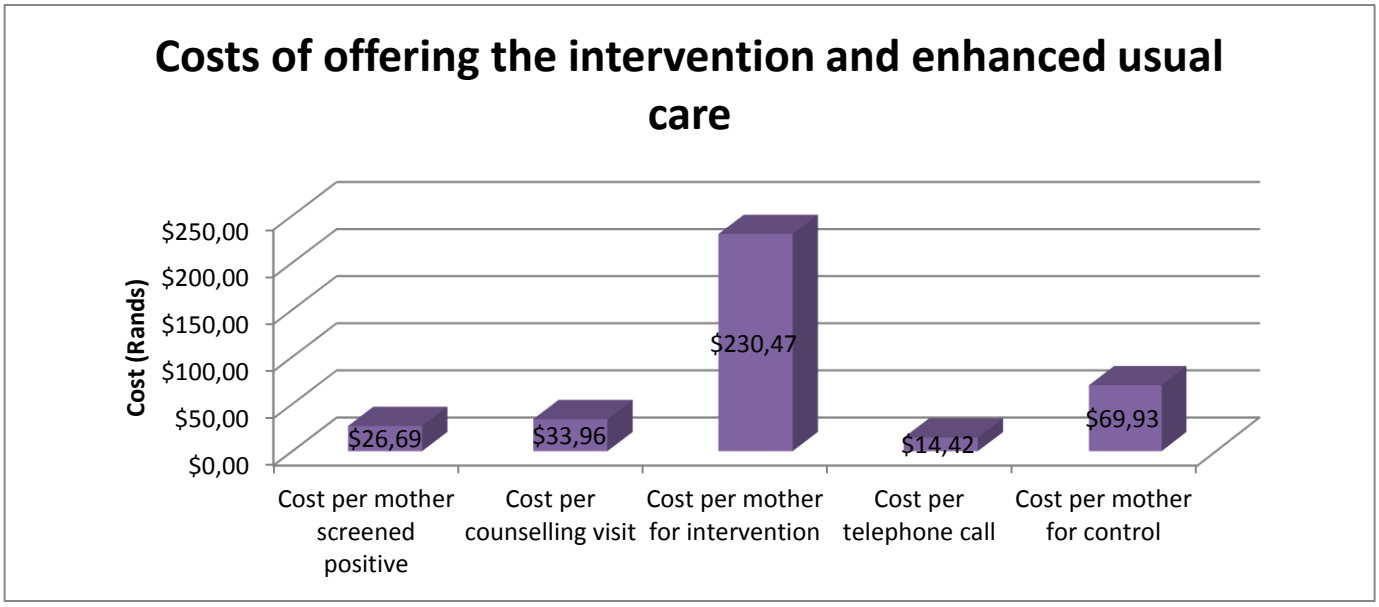
The total cost of the intervention for six counselling sessions was $54,136.70 while the enhanced usual care total cost was $20,423.78 (Table 5). Recurrent costs accounted for 60% of total intervention costs with salaries being the main cost driver, accounting for 45% of total costs ($24,546.16). Following salaries, screening costs ($11,341.74:21% of total costs) was the next cost driver for the intervention. On the other hand, start-up costs and cost of the rooms each accounted for 9% and 10% of total costs respectively. Costs of the enhanced usual care comprised of screening costs (56% of total costs), start-up costs (7% of total costs) and recurrent costs (37% of total costs).

Table 5: Intervention and enhanced care costs

	Intervention costs (US$)	%Costs within inputs	% of total costs	Enhanced care costs	%Costs within inputs	% of total costs
i.) Cost of Screening						
Subtotal	$11,341.74	100%	21%	$11,341.74	100%	56%
ii.) Start-up costs						
Development of manual	$3,065.56	62%		$1,216.49	81%	
Training	$250.84	5%		$18.81	1%	
Equipment & supplies	$1,597.90	33%		$268.87	18%	
Subtotal	$4,914.29	100%	9%	$1,504.17	100%	7%
iii.) Recurrent costs						
Salaries	$24,546.16	75.9%		$6,134.19	81%	
Transport	$5,370.77	16.6%		-	-	
Airtime & bundles	$2,365.24	7.3%		$412.21	5%	
Refreshments & Supplies	$67.80	0.2%		-	-	
Telephone costs & manual	-	-		$1,031.47	14%	
Subtotal	$32,349.97	100%	60%	$7,577.87	100%	37%
iv.) Cost of rooms						
Subtotal	$5,530.70	100%	10%	-	-	
TOTAL (US$)	**$54,136.70**		100%	**$20,423.78**		100%

As shown in figure 2, with a cost of $5.17 per mother screened for depression, the cost per mother screened positive totalled $26.69. The cost per counselling visit was $33.96 for the intervention arm while the cost per telephone call in enhanced usual care was $14.42. If delivered to completion without loss to follow-up, the cost for the interventions per mother was $230.47 versus $69.93 for enhanced usual care.

Figure *2*: Costs of offering the intervention and enhanced usual care



Sensitivity analysis

Screening costs were a key cost driver in this study, and a sensitivity analysis was used to determine cost differences if CHWs instead of field workers were employed to carry out the screening process. This was found to reduce the total screening costs by $15.08 woman screened positive (Table 6).

In this study, 19% of the participants screened positive for maternal depression. A sensitivity analysis was done where the prevalence of maternal depression was varied from 1% to 50%. This had an effect, as the cost per mother screened positive decreased as prevalence of maternal depression increased. This is illustrated in Table 6 below.

There is not a set interest rate to be used in all economic evaluations; therefore a sensitivity analysis on the interest rate was deemed appropriate. The interest rate used in this study was 8% based on the return of South Africa's long term bond. 3% interest rate is one that has been proposed [42] and used in a number of studies. In the sensitivity analysis, an interest rate of 0%, 3% and 8% were compared. This is shown in Table 7 below.

Table 6: Varying the cadre of staff screening and the proportion of women who screened positive

	Cost per mother screening positive	**Total Screening Costs**	**Total Intervention costs**
*Cadre of staff screening			
Field workers	$26.69	$11,341.74	$54,136.70
CHWs	$11.61	$4,935.57	$47,730.53
Prevalence (%screening positive)			
1%	$517.41		
15%	$34.49		
19%	$26.69		
35%	$14.78		
50%	$10.35		

*Costing at 19% prevalence rate as in the study

Table 7: Varying the interest rate of the intervention

	0%	3%	8%
Start-up costs	$3,955.85	$4,303.59	$4,914.29
Recurrent costs	$32,349.97	$32,349.97	$32,349.97
Cost of rooms	$2,075.85	$3,177.33	$5,530.70
Cost of screening	$9,967.70	$10,405.77	$11,341.74
Total intervention costs	$48,349.38	$50,236.66	$54,136.70
Cost per mother for the intervention	$206.22	$214.16	$230.47
Cost per visit	$30.46	$31.61	$33.96

Discussion

This study analysed the cost of health care utilisation among women with differing severity of maternal depression. The women with moderate/severe depression had more outpatient visits and longer hospital admissions, approximately 1.6 times longer admission days than those with mild depression. This, according to Bock et al [13], could be as a result of a delay in seeking health care among the depressed, leading to a need for more intense care once services are accessed.

The health service utilisation cost of untreated maternal depression over a period of three months was estimated to be $128.27, $76.78 and $19.70 per mother/child among those with moderate/severe depression, mild depression and no depression respectively: a cost difference of $108.57 per mother/child between the first and

the last group of women mentioned above. The results therefore show that health care costs of pregnant women increases as severity of depression increases. None the less, it is important to note that the pregnant women with no depression in this study are still psychologically distressed. This implies that the cost difference could have been greater if women with depression would have been compared to those who are not psychologically distressed.

The increased rates and cost of depression seen in this study are similar to those documented in previous studies. Previous studies have shown that women with postnatal depression have more outpatient and emergency visits as compared to those who do not have depression, and visit health care professionals more frequently [10, 11]. Potential reasons for the increased use of health care services among women with depression could be that the depression contributes to physical problems, therefore these women seek more care because they are more physically sick [46]. It could also be that depression reduces the immune system of these women making them more vulnerable to certain diseases; or women with depression make poor behavioural choices such as smoking or drug use that could lead to injury or even medical problems [46]. These are some potential hypotheses that require exploration in future research.

A majority of women with maternal depression are often silent, reluctant in seeking health care services and revealing that they are unhappy after the birth of their child [47]. It is therefore important to break this silence by offering information and support to these women. By doing so, the mother is able to cope better but also the provider may be able to avert some costs.

This study looks at a psychological intervention that could be used to offer support to women with maternal depression using a task shifting approach. The total cost of offering this intervention over a period of one year and eight months was $54,136.70 while the cost of offering enhanced usual care was $20,423.78. The results highlight that the cost per counselling visit was $33.96 while the cost per mother for the intervention was $230.47.

Screening costs accounted for 21% of total intervention costs. A sensitivity analysis shows that the costs of screening could be reduced by 56% if a lower cadre of staff is used for screening; CHWs instead of field workers.

The advantage of this study is that it provides the cost of offering a psychological intervention using low cadre staff through task shifting in a field where resources are scarce [18]. It highlights that at relatively low costs, it was possible to train CHWs who had no prior skills to deliver the intervention at costs that were cheaper than using a mental health specialist. Notwithstanding, the CHWs must be efficient as they offer the intervention. Salaries of staff were the major cost driver in this study. The CHWs spent 29.2% of their time offering the intervention to participants, which equates to one or two sessions offered in a day per CHW. The mental health counsellor would spend approximately 37.5% of her time offering supervision and support to the CHWs offering the intervention. While this study has only included the above proportions in estimating salary costs, costs would be higher if this down time were included. A key implication is that economies of scale and scope need to be carefully considered in intervention design so that any down time can be used productively.

Economies of scale applies where the average cost per visit or cost per mother would decrease as the number of women counselled increases [48]. In this case, economies of scale would be hard to attain because the number of women who are offered the intervention is highly dependent on the prevalence of maternal depression. Therefore, economies of scale could be better attained in areas with higher prevalence of maternal depression: as the sensitivity analysis showed the cost per mother screened decreases with increased prevalence.

However, it may be possible that economies of scope could help to achieve efficiencies: this is defined as it being cheaper to produce a range of products together than to produce each one individually [49]. The CHWs in this study spent 29.2% of their time offering the intervention. To attain economies of scope, this same CHW could be efficiently used in the clinic by not only offering maternal mental health counselling but in addition offering a variety of other counselling services for family planning or within the context of prevention of mother-to-child transmission of HIV (PMTCT) services. One mental health counsellor could also be used to oversee CHWs in a larger number of clinics in the area, ensuring his or her time is spent efficiently.

This study is important as it highlights the costs of offering the psychological intervention and therefore informs the policy maker on the affordability of the intervention. This is because affordability is not related to cost-effectiveness [50]. The policy maker would be able to gauge the affordability of the intervention based on the budget constraint. It is also important to note that if the intervention would be scaled up to a larger geographical area, it would need more attention in terms of capacity as opposed to the enhanced usual care. From a health professional point of view, there would need to be regular training, supervision, performance management as well as advocacy and mobilisation. On the other hand, from an organisational point of view, there would need to be standard operating procedures set for this intervention, as well as results monitoring and reporting [51].

One limitation of this study however, is that the final estimates excluded clinic overhead costs due to the unavailability of these costs. Therefore this study is more reflective of a situation where the psychologicalintervention is integrated into existing services without developing additional clinic capacity (e.g. through extending the building or opening hours). Another limitation of this study is that it was not able to determine whether offering the psychological intervention is effective or not. This is because a full economic evaluation was not possible at the time that this study was being conducted due to the unavailability of effectiveness data. It is also important to note that the screening tool and approach used in the trial could be different to that used in future implementation. The final limitation was that this study was using data that was already collected by the AFFIRM study prior to the commencement of this study. There could be no adaptations done on the questionnaire that was administered to the participants: For example the level of hospital that the participant visited was not indicated, therefore the use of a weighted average cost of hospital admission may have overestimated the health service utilisation costs. In addition, not having detailed information on the cause of admission or access to patients expenditure records resulted in the use of WC unit costs which may have had an effect on the costs.

If health care costs of pregnant women increases as the severity of maternal depression increases, as identified in this study, potentially a way of reducing these costs is to improve early detection and treatment for these

pregnant women and possibly include these services in antenatal care. Future studies should further unpack the health care utilisation patterns of women with maternal depression and establish the reasons for the increased costs. It would be beneficial to determine if the increased utilisation rates in South Africa are related to more psychiatric visits or if it as a result of mismanagement issues such as increased injuries or higher incidence of diarrhoea in children, among other issues. Further research should also look into the health utilisation costs of psychological distressed pregnant women in comparison to non-distressed pregnant women. This cost analysis study would feed into a full economic evaluation, and future studies could look into determining if this intervention was cost-effective or not.

Conclusion

This study has shown that women with maternal depression use more health services, and as a result, incur higher costs. It is possible to support women with maternal depression by offering psychological interventions. In South Africa, where psychologists and psychiatrists are scarce, a task shifting approach can be used where lower cadre staff can be trained to offer the intervention. According to this study, the average cost per counselling visit is $33.96. This cost may be affordable depending on the existing budget constraint. Despite the results displayed in this study that would go a long way in informing policy makers, further research determining the cost-effectiveness of this intervention would be important in decision making.

List of abbreviations used

- HIV/AIDS – Human immune deficiency virus/ Acquired immunodeficiency syndrome
- CHWs – Community health workers
- MINI – Mini-international neuropsychiatric interview
- AFFIRM – Africa Focus on Intervention Research for Mental Health
- US$ - United States Dollars

- SAR – South African Rand
- EPDS – Edinburgh postnatal depression scale
- US$/PDE – United States Dollar per patient day equivalent
- CD- compact disc
- PHC – Primary health care

Competing interests

The author has no competing interests.

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PART D: POLICY BRIEF

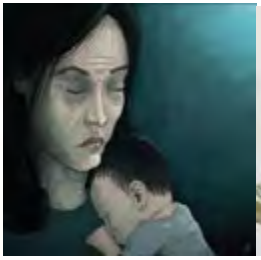
POLICY BRIEF

NOVEMBER 2015

Cost of untreated maternal depression and the cost of intervening using a task shifted psychological approach in Khayelitsha, South Africa:

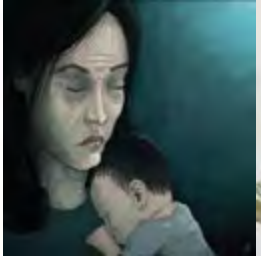
Do pregnant women with increasing severity of depression spend more on health care services than those without depression? How much would it cost to provide support to these women?

This policy brief is based on a study that assessed the health care utilisation patterns and costs of participants with maternal depression. In addition the study determined the costs of a psychological intervention offered by trained community health care workers to women with maternal depression. This study is part of a larger study: AFFIRM (Africa focus on intervention research for mental health) study. The aim of the AFFIRM study is to determine the effectiveness and cost-effectiveness of the intervention. This study was submitted as a mini-dissertation by Stacy Kwamboka Orangi to the Health Economics Division, Faculty of Health Sciences at the University of Cape Town under the supervision of Associate Professor Susan Cleary.



Executive Summary

Maternal depression is a public health problem with studies showing high prevalence rates in some areas of South Africa. The effects of maternal depression are felt by the mother and her children/family and may lead to economic losses. Psychological interventions can be offered by trained community health workers under the supervision of a mental health counsellor. Assessing the health care utilisation and costs of participants will enable us to determine the costs of untreated maternal depression. In addition to that, it would be of importance to determine the costs of offering supportive interventions to depressed expectant mothers. This study found that as the severity level of maternal depression increases, there is an increased use of health services and as a result higher health care costs are incurred. The study also determined the costs of offering a psychological intervention; which could be affordable depending on the budget constraint. This study also shows that the intervention could be less costly if screening were done by community health workers, if the intervention were targeted to settings with high maternal depression, and if it were to be integrated into antenatal care services.



Introduction

Maternal depression is a form of mental illness that is characterised by changes in mood and behaviour that can affect a mother during pregnancy and/or up to 12 months after giving birth (National Institute for Health Care Management 2010). In South Africa, maternal depression does not receive the deserved attention yet isolated studies show relatively high prevalence rates (Rochat et al. 2011; Honikman et al. 2012; Cooper et al. 1999).This could be as a result of the lack of sufficient resources in mental health (World Health Organization 2011). Maternal depression is a public health problem for a number of reasons including the possibility of pre-term labour, increased risky behaviour and complications during pregnancy (World Health Organization 2008). The effects could also be far reaching to the infant as well as to the economy of the country (Zuckerman & Beardslee 1987; Berto et al. 2000). As a result of these effects, depressed women would tend to seek more health care for themselves or their children leading to increased health care costs. It **could therefore be costing South Africa more to leave maternal depression untreated, than it may cost to treat it** (Bateman 2014). Psychological approaches as a form of treatment for maternal depression may be more acceptable to pregnant and breastfeeding mothers than prescription medication (Hanlon 2013).

Source (Shatsa County n.d.)

In 2014, the Africa Focus on Intervention Research for Mental Health (AFFIRM) study started a randomised controlled trial in Khayelitsha, South Africa (Lund et al. 2014). In this trial, pregnant women either receive the intervention or enhanced usual care. Women in the intervention arm were offered treatment through a psychological approach delivered by trained community health care workers. The purpose of this brief is to present the costs of untreated maternal depression by analysing the health care utilisation patterns of women with maternal depression early in their pregnancy. This study also presents the costs of CHW-delivered support or treatment for these women.

Box 1: Description of Intervention and enhanced usual care in AFFIRM study

- *The intervention arm: Women in this group were offered a psychological intervention. This involved 6 counselling sessions of one hour in duration offered by trained community health workers (CHWs)*

- *The control group: Women in this group received enhanced usual care. Usual care focusses on the foetal and later infant immunisation and development. In addition to this, the women received regular monthly phone calls over a period of 3 months. This was done by CHWs who were not trained to offer the intervention.*

A mental health counsellor offered supervision and support to the CHWs in both groups.

Methods

Data collected during the first antenatal visit and the Western Cape Department of Health Annual Report 2014/2015 was used to analyse the cost of depression. Both provider costs and patient costs were determined.

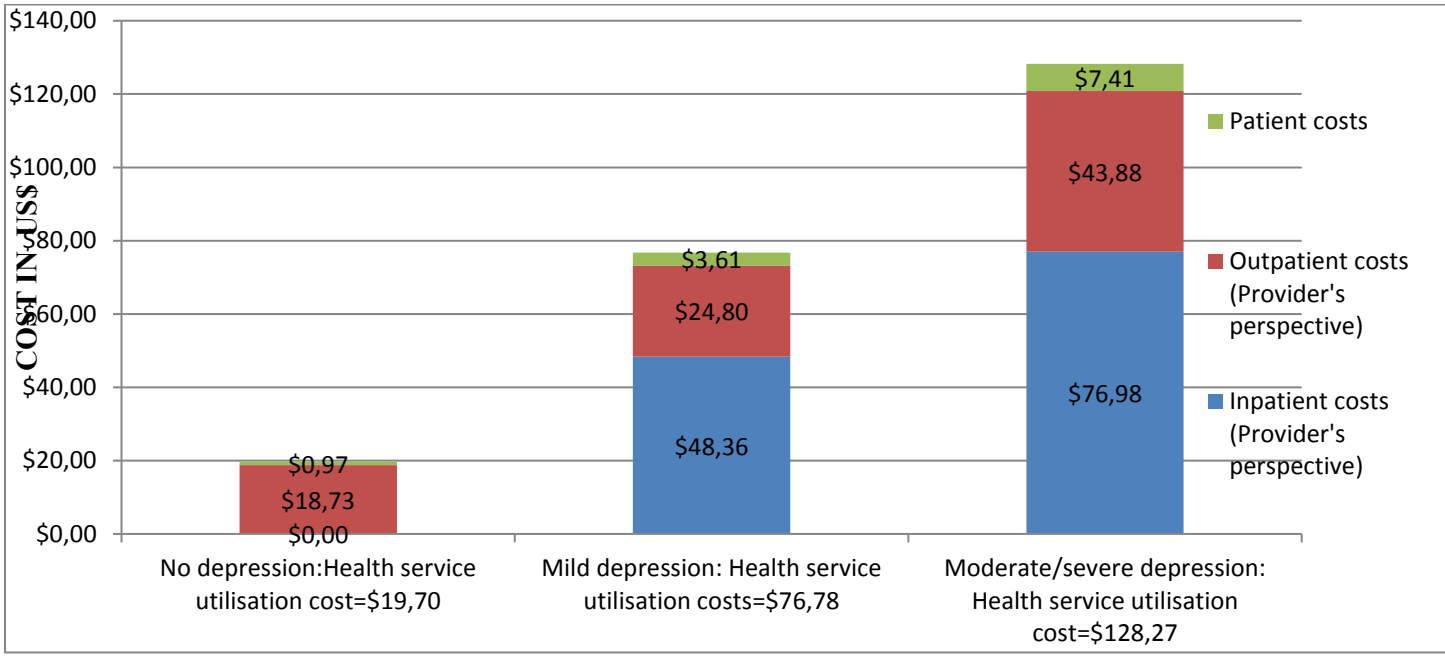
To determine the costs of the intervention and enhanced usual care, data obtained from the project manager of AFFIRM and market prices were used. This was done using 2014/2015

prices and reported from a providers perspective. The time period of these costs was 1 year and 8 months (duration of the intervention).

Key findings

- Women with moderate/severe depression used more health services, and incurred higher costs, than those without depression.
- Put together, the health service utilisation cost (public sector cost, and patient costs) of moderate/severe untreated maternal depression were almost seven times the costs for women without depression. This is illustrated in figure 1 below.

Figure 1: Comparison of costs of depression between pregnant women with different severity levels of depression

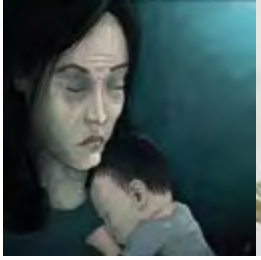


- The provider cost per mother for the intervention was $230.47 versus $69.93 for enhanced usual care.

- Salaries were the main cost driver of the intervention accounting for 76% of all recurrent costs. The costs of the intervention would have been much greater if more specialised staff were used instead of CHWs.
- In this study, field workers were the staff used to conduct the screening process. Screening costs would be decreased by $15.08 per woman screened positive if CHWs would have been used during the screening process instead of fieldworkers.

Policy recommendations

- ✓ The use of trained CHWs to deliver the intervention can save money and enhance access to mental health care.
- ✓ It is cheaper to offer the intervention in areas where the prevalence of maternal depression is high. In addition, it is more efficient to integrate the system into routine antenatal care. If possible the use of one CHW to offer counselling to not only depressed mothers but other conditions as well would be recommended to avoid down time.
- ✓ According to this study, the provider costs of untreated moderate/severe maternal depression are $120.86 per mother for a period of 3 months. In contrast, $230.47 per mother would be needed to offer psychological support over the same time frame. While



this treatment may avert some of the other provider costs, more research is needed to understand the impact of the intervention for both costs and outcomes.

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PART E: APPENDICES

Appendix 1: Informed consent form for AFFIRM study

AFFIRM RANDOMIZED CONTROLLED TRIAL

INFORMED CONSENT FORM FOR PARTICIPANTS

The Research Study

We are asking you to participate in this research study. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

The University of Cape Town is doing this project to research maternal mental health in pregnant women in Khayelitsha. The project is called AFFIRM (**AF**rica **F**ocus on **I**ntervention **R**esearch for **M**ental health), which is a collaboration between the University of Cape Town, University of Addis Ababa, Columbia University, Johns Hopkins University, Kings College University, Makerere University, and the Department of Health. It is funded by the National Institutes of Health, USA.

Why is it important?

The study is important because one out of every three women in Khayelitsha experience depression or anxiety when they are pregnant or after having a baby.

What is it for?

This study is looking at ways to provide counselling services and mental health assistance to depressed pregnant women, so that they can learn to manage and cope with maternal distress.

We want to find out how best to use a "task-shifting" approach, which means using community health workers instead of psychologists and psychiatrists, to provide counselling services for depression. We want to develop appropriate and cost effective mental health services for these women, and we hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

Who will be involved?

1. 420 pregnant women at their first antenatal booking at Michael Mapongwana Community Health Centre Midwife Obstetrics Unit (MOU) and Site B Community Health Centre MOU, who

show symptoms of depression when assessed on the Edinburgh Postnatal Depression Scale (EPDS).

2. Community Health workers who work in the catchment area of Michael Mapongwana Community Health Centre and Site B Community Health Centre.

3. Registered Nurse Midwives based at Michael Mapongwana Community Health Centre and Site B Community Health Centre, who work with perinatal mothers and/or mental health in Khayelitsha.

4. Service managers at Michael Mapongwana Community Health Centre and Site B Community Health Centre.

How long will it last? The study will run from July 2012 to July 2015.

What will it mean if you participate in the study?

If you agree to participate in this study you will be asked a few screening questions about depression with the EPDS. If you are distressed according to the EPDS, we will continue with an interview which will take approximately one hour. The interviews will ask some sensitive questions and all information you give us will be kept strictly confidential. You can refuse to answer any questions that you feel uncomfortable answering. The information you give us will be used to help us design a cost effective counselling intervention to help mothers who are suffering from depression.

After this, you will EITHER receive 6 counselling sessions when you come for your pregnancy check-ups, OR monthly telephone calls from a community health worker to discuss your depression and ways to help to improve it. The counselling sessions will be conducted approximately every two weeks at the clinic or at the participant's home (by prior arrangement). These counselling sessions will be scheduled to align as closely as possible with routine antenatal check-ups at the clinic. You would then attend the counselling session either before or after your antenatal check-up. If it does not align with your check-up, the community health worker will schedule a visit to the clinic that best suits you. The sessions will be audio recorded to ensure the quality of the counselling. You will then be asked to participate in three more interviews at: one month before birth, three months after birth, and twelve months after birth. We intend to conduct the interviews and counselling sessions on the same days you come for your pregnancy and baby check-ups at the clinic so that you will not incur any additional costs. In the interviews after your baby is born we will also ask some questions about your baby. We will

inform you if any new findings arise during the duration of the study that may affect your participation.

Is there any disadvantage from participating in this study?

There is the possibility that you may have a mental health problem or that participating in the study may remind you of a time that you had such a problem. The risks associated with worsening of your depression are present whether or not you participate in this study. If you get distressed by a mental health problem or feel suicidal, we will refer you for psychological help. If you have a serious substance abuse problem or psychiatric illness that was not initially picked up at the interview, we will refer you for external assistance and you will no longer be able to participate in the study.

If you receive counselling from us, there a small risk that counsellors may breech confidentiality and/or disclose personal information to you or others. We will minimize this risk by careful evaluation of the counsellors and through weekly group supervision and monthly individual supervision for them. If you report or the counsellors observe any child abuse, we are obliged by law to report this to the Department of Social Development. This means that we will need to give information about your child to the social worker.

Is there any advantage to the study?

We hope that the counselling will improve your mental health and help you to build better ways of coping with depression in the future. We also hope that the information obtained will help to improve mental health services in South Africa and other countries in sub-Saharan Africa.

What alternatives do I have if I don't participate in the study?

If you think you are depressed but you do not want to participate in the study, you can contact one of the organisations listed in the pamphlet we give you, and they can help you.

What if I change my mind later?

You are free to withdraw at any stage from participating in the study and your decision will not disadvantage you in any way. You will need to inform a member of the project if you wish to withdraw, and if you require, we can refer you to relevant local mental and social health services.

Who will see the information that we collected?

All records will be kept completely confidential, and stored electronically at the University of Cape Town (UCT). Your identity will be anonymous and your information will be combined with that of all the other participating women. After the information is analysed, the recordings

and transcripts will be destroyed. This information will only be seen by the researchers and investigators.

When we have finished the study, the information that you provide to us could be used by researchers outside of this study. However, your name and personal details will never be given to any of these researchers. They will never be able to identify who you are.

Who to contact if you want to know more, or if you have a problem at any time?

If you want more information on the study before deciding whether or not to participate, or if you participate and later need help or have questions, please contact:

Prof C. Lund, Department of Psychiatry and Mental Health, University of Cape Town,

Tel: 021 685 0120

If you have any questions about your rights and welfare in the research, please contact:

The Human Research Ethics Committee, Groote Schuur Hospital.

Tel: 021 406 6626

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[14] School of Public Health and Family Medicine, Health Economics Division, University of Cape Town

Consent to Enroll **Research ID #**

I, _____ agree to participate in the research study on maternal mental health in Khayelitsha, to help to develop relevant and cost effective ways of helping mothers with depression.

I have received and understood the study information sheet. I have discussed the advantages and disadvantages of participating in the study and I agree to participate in the interviews as stated in the information sheet.

I know I can leave the research study at any time without prejudice and be referred for psychological help if need be.

Signature: _____

Date: _____

Witness
Name: _____

Signature: _____

Date: _____

You may keep the information sheet. The signed consent form will remain in our study files.

Appendix 2: Baseline questionnaire for the AFFIRM study

AFFIRM ENGLISH Baseline assessment

1. **Date of interview:**
2. **Initials of Data Collector:**

11.12 These questions are completely confidential and will only be used by UCT and to help you. We are not connected to any banks or SARS or ALLpay or any funding or loans or grants. We will not give or take any money from you. The purpose is only to find out information about your health, and help you with it by providing support from community health workers and counsellors.

Section 2.Baseline Identifiers and Contact Information

2.1. Has the mother given consent?

If no, (27.1.) **Why not? _____**

2.2. PID: _____

2.5 First Name of participant: _____

2.6 Surname of participant

2.7 Address of Participant: _____

Section 3.Baseline Demographics

3.1 Total number of pregnancies including this one: _____

3.2 Total number of live births: _____

3.3 Gestation period for this pregnancy (Response must be not more than 6 and a half months, or 26 weeks)**: ____**

3.4 Participant's home language:

1. Xhosa
2. English
3. Other - Specify _____

3.6 Language of the interview:

1. Xhosa
2. English

3.7 How old are you?

3.8 What is your population group?

1. African
2. Indian
3. Coloured
4. White
5. Other

3.9 What is the highest grade you have completed? [No Schooling], [1], [2], [3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [Diploma/degree]

3.10 When is your baby due? _____

Section 4. Demographics for All Timepoints

4.4 Are you currently working?

1. Employed full time permanently

2. Employed part-time permanently
3. Do casual/piece jobs
4. Self employed
5. Unemployed and looking for work
6. Unemployed and not looking for work
7. Post Matric studying
8. Still in school

4.5 Which income amount best describes the money you get personally every month?

1. R0
2. R1 - R500
3. R501 - R1000
4. R1001 – 2000
5. R2001 – 5000
6. More than R5000
7. Refused
8. Don't know

4.6 What is your main source of income?

1. My own business
2. Salary or wage
3. Husband or partner
4. Social grant
5. Family
6. I have no income
7. Other (Specify_____)

4.8 What government grants or pensions do you and other people in your household receive?

1. Child support grant
2. Care dependency grant (disability grant for children)
3. Foster care grant
4. Disability grant (disability grant for adults)
5. Old age pension
6. Other (Specify _____)
7. No Grants

4.10 Do you have a partner and do you live together?

1. Yes and we live together
2. Yes, but we do not live together
3. No, and I live with my family
4. No and I live alone (with or without baby)

4.11 If you have a partner, what is his main source of income?

1. Own business
2. Salary or wage
3. You as his partner
4. Social grant
5. Family
6. He has no income

4.12 Do you own any of the following:

1. House
2. Flat
3. Shack

4. None
5. Refused
6. Don't know

4.13 What type of dwelling or home do you live in?

1. Shack/informal dwelling
2. Backyard Dwelling
3. Formal house
4. Flat/ council house
5. Other (Specify_____)

4.15 Including yourself, how many adults live in your home? _____

4.16 How many children live in your home? _____

4.17 How many rooms in total do you have in your dwelling? _____

4.18 How many people sleep in the same room that you sleep in? _____

4.19 What is the total income for your household per month? (include all money coming in including grants and money from family)

1. R0
2. R1 - R500
3. R501 - R1000
4. R1001 – 2000
5. R2001 – 5000
6. More than R5000
7. Refused
8. Don't know

4.20 Is this amount the same every month?

1. Yes, the same every month
2. Yes, most of the time it is the same
3. No, it varies a lot each month
4. Don't know

4.21 Do you have electricity at home? YES NO

4.22 Where do you get water for the household?

1. In the dwelling
2. In the yard
3. From a neighbour's yard
4. From a public tap
5. We have no regular access to water
6. Other (Specify_____)

4.24 What type of toilet do you have?

1. A flush toilet inside the dwelling
2. A flush toilet outside the dwelling
3. Communal flush toilet
4. Bucket system or pit latrine

4.25 Where do you shop for food and other groceries?

1. Supermarkets
2. Local spaza shop
3. Other
4. N/A I don't shop

4.26 Which of the following do you have?

1. A bank account (yes/no)

2. An ATM card (yes/no)
3. A credit card (yes/no)
4. Informal savings scheme (e.g. stokvel)
5. None of these

4.27 Are you currently taking any medication prescribed by a medical doctor or nurse? YES / NO

4.28 What is the medication for?

1. Physical illness
2. Psychiatric illness
3. Other (please specify) _____
4. Don't know

SECTION 7. Edinburgh Postnatal Depression Scale (EPDS)

In this next section, we will READ you STATEMENTS about how you have been feeling recently. Please provide the answer that comes closest to how you have felt IN THE PAST 7 DAYS, not just how you feel today

IN THE PAST 7 DAYS:

1. I have been able to laugh and see the funny side of things

- ☐ As much as I always could [0]
- ☐ Not quite so much now [1]
- ☐ Definitely not so much now [2]
- ☐ Not at all [3]

2. I have looked forward with enjoyment to things

- ☐ As much as I always did [0]
- ☐ Rather less than I used to [1]
- ☐ Definitely less than I used to [2]
- ☐ Hardly at all [3]

3. I have blamed myself unnecessarily when things went wrong

- ☐ Yes, most of the time [3]
- ☐ Yes, some of the time [2]
- ☐ Not very often [1]
- ☐ No, never [0]

4. I have been anxious or worried for no good reason

- ☐ No, not at all [0]
- ☐ Hardly ever [1]
- ☐ Yes, sometimes [2]
- ☐ Yes, very often [3]

5. I have felt scared or panicky for no good reason

- ☐ Yes, quite a lot [3]
- ☐ Yes, sometimes [2]
- ☐ No, not much [1]
- ☐ No, not at all [0]

SCORE_____

6. Things have been getting on top of me

- ☐ Yes, most of the time I haven't been able to cope at all [3]
- ☐ Yes, sometimes I haven't been coping as well as usual [2]
- ☐ No, most of the time I have coped quite well [1]

- No, I have been coping as well as ever [0]

7. I have been so unhappy that I have had difficulty sleeping

- Yes, most of the time [3]
- Yes, sometimes [2]
- Not very often [1]
- No, not at all [0]

8. I have felt sad and miserable

- Yes, most of the time [3]
- Yes, quite often [2]
- Not very often [1]
- No, not at all [0]

9. I have been so unhappy that I have been crying

- Yes, most of the time [3]
- Yes, quite often [2]
- Only occasionally [1]
- No, never [0]

10. The thought of harming myself has occurred to me

- Yes, quite often [3]
- Sometimes [2]
- Hardly ever [1]
- Never [0]

SECTION 8. MINI International Neuropsychiatric Interview (MINI 6.0.0)

A. MAJOR DEPRESSIVE EPISODE

(↓ MEANS : GO TO THE DIAGNOSTIC BOXES, CIRCLE **NO** IN ALL DIAGNOSTIC BOXES, AND MOVE TO THE NEXT MODULE)

A1 a Were you ever depressed or down, most of the day, nearly every day, for two weeks? NO YES

IF NO, CODE NO TO **A1b**: IF **YES** ASK:

b For the past two weeks, were you depressed or down, most of the day, nearly every day? NO YES

A2 a Were you ever much less interested in most things or much less able to enjoy the things you used to enjoy most of the time, for two weeks? NO YES

IF NO, CODE NO TO **A2b**: IF **YES** ASK:

b In the past two weeks, were you much less interested in most things or much less able to enjoy the things you used to enjoy, most of the time? NO YES

IS **A1a** OR **A2a** CODED **YES**? NO YES

A3 IF **A1b** OR **A2b** = **YES**: EXPLORE THE **CURRENT** AND THE MOST SYMPTOMATIC **PAST** EPISODE, OTHERWISE IF **A1b** AND **A2b** = **NO**: EXPLORE ONLY THE MOST SYMPTOMATIC **PAST** EPISODE

Over that two week period, when you felt depressed or uninterested:

	Past 2 Weeks	Past Episode
a Was your appetite decreased or increased nearly every day? Did your weight decrease or increase without trying intentionally (i.e., by ±5% of body weight or ±8 lb or ± 3.5 kg, for a 160 lb/70 kg person in a month)? IF **YES** TO EITHER, CODE **YES**.	NO YES	NO YES
b Did you have trouble sleeping nearly every night (difficulty falling asleep, waking up in the middle of the night, early morning wakening or sleeping excessively)?	NO YES	NO YES
c Did you talk or move more slowly than normal or were you fidgety, restless or having trouble sitting still almost every day?	NO YES	NO YES
d Did you feel tired or without energy almost every day?	NO YES	NO YES
e Did you feel worthless or guilty almost every day?	NO YES	NO YES

IF **YES**, ASK FOR EXAMPLES.

THE EXAMPLES ARE CONSISTENT WITH A DELUSIONAL IDEA. Current Episode ⑦ No ⑦ Yes
Past Episode ⑦ No ⑦ Yes

f Did you have difficulty concentrating or making decisions almost every day? NO YES
NO YES

g Did you repeatedly consider hurting yourself, feel suicidal, NO YES
NO YES
or wish that you were dead? Did you attempt suicide or plan a suicide?
IF **YES TO EITHER, CODE YES.**

A4 Did these symptoms cause significant problems at home, at work, socially, NO YES
NO
YES
at school or in some other important way?

A5 In between 2 episodes of depression, did you ever have an interval
of at least 2 months, without any significant depression or any significant loss of interest?
NO
YES

ARE **5** OR MORE ANSWERS (**A1-A3**) CODED **YES** AND IS **A4** CODED YES FOR THAT TIME FRAME?

SPECIFY IF THE EPISODE IS CURRENT AND / OR PAST.

IF **A5** IS CODED **YES,** CODE **YES** FOR RECURRENT.

NO	**YES**
MAJOR DEPRESSIVE EPISODE	
CURRENT	⑦
PAST	⑦
RECURRENT	⑦

A6 a How many episodes of depression did you have in your lifetime? _____

Between each episode there must be at least 2 months without any significant depression.

SECTION 11. MINI SUICIDALITY

In the past month did you:

B1 Suffer any accident? This includes taking too much of your medication accidentally. NO YES
0 IF NO TO B1, SKIP TO B2; IF YES, ASK B1a:

B1a Plan or intend to hurt yourself in any accident either actively or passively
(e.g. by not avoiding a risk)? NO YES
0 IF NO TO B1a, SKIP TO B2: IF YES, ASK B1b:

B1b Intend to die as a result of any accident? NO YES 0

B2 Feel hopeless? NO YES 1

B3 Think that you would be better off dead or wish you were dead? NO YES 1

B4 Think about hurting or injuring yourself or have mental images of harming yourself, NO YES 4
with at least some intent or awareness that you might die as a result?

How many times? _____

B5 Think about suicide (killing yourself)? NO YES 6
How many times? _____

IF NO TO B5, SKIP TO B7. OTHERWISE ASK:

Frequency		Intensity	
Occasionally	⑦	Mild	⑦
Often	⑦	Moderate	⑦
Very often	⑦	Severe	⑦

B6 Feel unable to control these impulses? NO YES 8

B7 Have a suicide method or plan in mind (e.g. how, when or where)? NO YES 8
IF NO TO B7, SKIP TO B9.

B8 Intend to follow through on a suicide plan? NO YES 8

B9 Intend to die as a result of a suicidal act NO YES 8

B10 Take any active steps to prepare to injure yourself or to prepare for a suicide attempt in which you expected or intended to die NO YES 9
How many times? _____

B11 Injure yourself on purpose without intending to kill yourself NO YES 4

B12 Attempt suicide (to kill yourself)? NO YES 9
A suicide attempt means you did something where you could possibly be injured, with at least a slight intent to die.
IF NO, SKIP TO B13:
How many times? _____
Hope to be rescued / survive ⑦
Expected / intended to die ⑦

In your lifetime:

B13 Did you ever make a suicide attempt (try to kill yourself)? NO YES 4
"A suicide attempt is any self injurious behavior, with at least some intent (> 0) to die as a result or if intent can be inferred, e.g. if it is clearly not an accident or the individual thinks the act could be lethal, even though denying intent."
(C-CASA definition). Posner K et al. Am J Psychiatry 164:7, July 2007.

IS AT LEAST **1** OF THE ABOVE (EXCEPT B1) CODED **YES**?

NO
YES

IF YES, ADD THE TOTAL POINTS FOR THE ANSWERS (B1-B13) CHECKED 'YES' AND SPECIFY THE SUICIDALITY SCORE AS INDICATED IN THE DIAGNOSTIC BOX:

SUICIDALITY CURRENT

1-8 points Low ⑦
9-16 points Moderate ⑦
≥ 17 points High ⑦

MAKE ANY ADDITIONAL COMMENTS ABOUT YOUR ASSESSMENT OF THIS PATIENT'S CURENT AND NEAR FUTURE SUICIDALITY IN THE SPACE BELOW:

SECTION 14. Health Care Utilisation Questionnaire (HCUQ)

14.1 I would now like to know about your recent experiences with obtaining health care for yourself and your children.

14.2 In the last 6 months, have you or any of your children ever stayed overnight in a hospital?
Yes [1]
No [0]
14.3 How many times have you or your children been admitted into hospital in the last 6 months?

Section 15.Health Care Utilization - Hospital Admission Details

15.1 For admission #REPEAT IDX, was it you or one of your children who was admitted?
Myself [1]
This child [2]
One of my other children [3]
15.2 For admission #REPEAT IDX, why were you/ your child admitted?
Infectious disease (e.g. malaria) [1]
Maternal/ perinatal condition [2]
Flu or cough [respiratory infection] [3]
Diarrhoea [4]
Injury [5]
Sleep problems [6]
Depression or anxiety [7]
Alcohol problems [8]
Other mental health problems [9]
Other chronic disease (e.g. heart, diabetes) [10]
Other condition [77] Please specify: _____
Don't know [888]
15.4 Where was the admission?
Charity/ church-run hospital [1]
Private hospital [2]
Government hospital [3]
15.5 How long was the admission (in days)?
15.6 How much did you, your family or friends have to pay in total (for hospital fees, medicines, investigations) IN RANDS?

Section 16.Health Care Utilization - Outpatient Care Count
16.1 In these next few questions, I dont want you to think about inpatient care, antenatal care or well baby visits. IN THE LAST 3 MONTHS, did you or your children see any health care providers? (For example: Traditional healer/ community health worker/ general nurse/ Pharmacist/ Psychiatrist/ psychiatric nurse/ mental health worker, social worker/ medical doctor/ other health care provider?)
Yes [1]
No [0]
16.2 How many times in the last 3 months did you/ your children see any of these health care providers?
Repeat this section for value of NumOtherProviders (16.2)
Section 17.Health Care Utilization - Outpatient Care Details
17.1 For the outpatient visit number #REPEAT IDX, was it you or one of your children who was seen?
Myself [1]
This child [2]

One of my other children [3]
17.2 For the outpatient visit number #REPEAT IDX, who did you/ one of your children see?
Traditional healer [1]
Community health worker [2]
Nurse / midwife [3]
Pharmacist [4]
General doctor [5]
Specialist doctor [6]
Psychiatrist [7]
Other mental health worker [8]
Social worker [9]
Psychiatric nurse [10]
Don't know [888]
Other [77] Please specify: _____
17.4 Where did you see them?
Your own home [1]
Local health centre [2]
Private office [3]
Hospital outpatient [4]
CHW's home [5]
17.5 Why did you have this visit?
Infectious disease (e.g. malaria) [1]
Maternal / perinatal condition [2]
Flu or cough [respiratory infection] [3]
Diarrhoea [4]
Injury [5]
Sleep problems [6]
Depression or anxiety [7]
Alcohol problems [8]
Other mental health problems [9]
Other chronic disease (e.g. heart, diabetes) [10]
Other [77] Please specify:_____
Don't know [888]
17.7 What were the main features of the visit? (list up to three elements)
Assessment and/or diagnosis [1]
Drug prescription (for condition listed previously) [2]
Drug prescription (for other condition) [3]
Psychosocial support / care [4]
Follow-up visit [5]
Referral (to other provider) [6]
Blood test or other test [7]
Xray [8]
Other [77]
Don't know [888]
17.8 How long did it take you to travel to where you received care for this visit? (single journey, in minutes).
17.9 How long did you wait for your consultation (in minutes)
17.10 How long was the consultation (excluding waiting time) in minutes?
17.11 How much did you, your family or friends have to pay in total in consultation fees? (IN RANDS)
17.12 How much did you, your family or friends have to pay in total for travel for this visit?

SECTION 18. WHO Disability Assessment Schedule (WHO-DAS) 2.0.0 (12 item version)

These next questions ask about difficulties due to health conditions. Health conditions include diseases or illnesses, health problems that may be short or long lasting, injuries, and mental or emotional problems. Think back over the past 30 days and answer these questions, thinking about how much difficulty you had doing the following activities.

a) How do you rate your overall health in the past 30 days? (*Read choices to respondent.)*

1 =Very good
2 = Good
3 = Moderate
4 = Bad
5 =Very Bad

b) In the last 30 days, how much difficulty did you have in:

	None	Mild	Moderate	Severe	Extreme/ Cannot Do
1. Standing for long periods such as 30 minutes?	0	1	2	3	4
2. Taking care of your household responsibilities?	0	1	2	3	4
3. Learning a new task, for example, learning how to get to a new place?	0	1	2	3	4
4. How much of a problem did you have joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	0	1	2	3	4
5. How much have you been emotionally affected by your health problems?	0	1	2	3	4
6. Concentrating on doing something for ten minutes?	0	1	2	3	4
7. Walking a long distance such as a kilometre [or equivalent]?	0	1	2	3	4
8. Washing your whole body?	0	1	2	3	4
9. Getting dressed?	0	1	2	3	4
10. Dealing with people you do not know?	0	1	2	3	4

11. Maintaining a friendship?	0	1	2	3	4
12. Your day to day work?	0	1	2	3	4
Now think about the last 30 days, or the last 4 weeks:					
13. Overall, in the past 30 days, how many days were these difficulties present? (DIFFICULTIES TOTAL)	RECORD NUMBER OF DAYS ___/___				
14. In the past 30 days, for how many days were you totally unable to carry out your usual activities or work because of any health condition? (TOTALLY UNABLE)	RECORD NUMBER OF DAYS __/__				
15. In the past 30 days, not counting the days that you were totally unable, for how many days did you cut back or reduce your usual activities or work because of any health condition? (CUT BACK)	RECORD NUMBER OF DAYS __/__				

SECTION 19. Cape Town Functional Assessment Instrument for Maternal Depression

I am going to ask you about different tasks and activities that you do currently in your everyday life. Thinking about the last 2 weeks, how much difficulty do you have doing the following tasks and activities?

Task or activity	**Degree of difficulty completing task or activity**					
	No difficulty	a little or some difficulty	a lot of difficulty (but can still do task)	Often can't do task or activity at all	Can never do task or activity	Not applicable
1. Cleaning the house	0	1	2	3	4	5
2. Preparing and cooking food for the family	0	1	2	3	4	5
3. Doing laundry	0	1	2	3	4	5
4. Bathing yourself	0	1	2	3	4	5
5. Taking part in community meetings	0	1	2	3	4	5
6. Taking care of the physical needs of babies and children (bathing, feeding, preparing for crèche or school, taking to crèche and school, keeping them safe; etc.)	0	1	2	3	4	5
7. Playing with your children and loving them	0	1	2	3	4	5

8. Spending time and doing activities with family and friends	0	1	2	3	4	5
9. Exercising	0	1	2	3	4	5
10. Doing volunteer work	0	1	2	3	4	5

SECTION 20. Hamilton Depression Rating Scale (HDRS)

20.2 During the past month, have you been less able than usual to work or do your usual activities? Do your activities make you feel tired, or have you lost interest in your activities?

0 No decrease in productivity or time spent at work and/or doing usual activities
1 Activities make you feel tired
2 Lost interest in work or activities
3 Decrease in productivity of work or activities
4 Spending less time at work or doing activities

20.3 **Have you gained or lost any weight during the past month?**

0 No
1 Possibly
2 Yes, definite change in weight (not on diet)

20.4 During the past month, have you experienced a loss of appetite?

0 No loss of appetite
1 Some loss of appetite but still eating
2 At least some loss of interest in food and requires encouragement to eat

20.5 During the past month, have you had an interest in sex?

0 Yes, normal interest in sex (or is not sexually active)
1 Somewhat less interest
2 A lot less interest than usual or no interest at all

20.6 The following 3 questions will ask you about different aspects of sleep: going to sleep at night, waking up in the middle of the night, and waking up early or sleeping late in the morning. Firstly, during the past month, have you had troubles or difficulties falling asleep?

0 No
1 Sometimes
2 Yes, almost every night has difficulty

20.7 During the past month, have you been waking up during the night?

0 No
1 Sometimes
2 Yes, almost every night has difficulty and gets out of bed, other than for urinating/ peeing.

20.8 During the past month, have you either been waking up earlier in the morning than you wanted to or sleeping too much?

0 No

1 Sometimes
2 Yes, wakes early and cannot go back to sleep, or sleeps too much most of the time

20.9 During the past month, have you experienced fatigue or had less energy than usual? Or have you had headaches, backaches, or aches in specific parts of your body?

0 No loss of energy, fatigue, or body aches
1 Some loss of energy and body aches
2 Yes, marked loss of energy, and/or has a clear symptom of pain, e.g., headaches or local muscle aches

20.10 During the past month, have you been feeling guilty or bad about something you have done? Do you feel you have let people down or that you are evil? Do you think your illness is punishment for something?

0 No feelings of guilt
1 Feels she has let people down
2 Feels she has let people down AND feels evil or bad
3 Thinks that her illness is a punishment
4 Hears voices or feels that her badness will hurt others or will lead to her own death

20.11 During the past month, have you been feeling nervous, anxious, worried or frightened?

0 Never
1 Sometimes
2 Quite often
3 Most of the time
4 Yes, severe symptoms all the time which are incapacitating or disabling

20.12 Now I am going to read you a list of physical symptoms. Tell me if you experience any of these and how severe they are.

A. Stomach or digestive problems or pains
B. Heart palpitations
C. Breathing very fast or trouble breathing
D. Urinating often
E. Muscle aches, body aches
F. Unusual sensations like trembling or ringing in your ears
G. Flushing, feeling faint, or sweating

Code for the most severe symptom:

0 Absent
1 A little bit
2 Some
3 A lot
4 Severe and incapacitating problem

20.13 During the past month, have you been worrying more than usual about your health and how your body is working? (Apart from normal fears about your pregnancy)

0 Not worried at all
1 Some unnecessary worry about her health
2 A lot of unnecessary worries about her health
3 Strong beliefs she has a physical problem and doctors won't believe her
4 Delusional, i.e., has false beliefs, eg. Thinks her body is rotting

20.14 During the past month, have you had thoughts that life is not worth living, or that you would rather be dead? Have you had thoughts of hurting or killing yourself?

0 No
1 Sometimes
2 Often
3 Most of the time
4 Suicide attempt

20.15 Do you think that you have a psychological problem, such as depression?

0 Acknowledges being depressed or having a psychological problem (OR is not currently depressed)
1 Acknowledges illness but blames it on something else
2 Denies any illness but is currently depressed in interviewer's opinion

20.16 During the past month, have you been feeling sad, depressed, helpless, hopeless, or worthless? If yes, how often do you feel this way?

0 No, not at all
1 Occasionally
2 Quite often
3 Very often
4 Yes, almost all the time

20.17 Observe and rate slowness of thought, speech, concentration, and physical movement (Observation only)

0 Normal speech and thought
1 Slight retardation (a bit of slowness in thinking or speaking)
2 Obvious retardation (a lot of slowness in thinking or speaking)
3 Interview difficult (a lot of very long pauses)
4 Interview impossible

20.18 Observe and rate restlessness, fidgetiness and physical activity (Observation only)

0 None
1 Fidgetiness
2 Playing with hands, hair, obvious restlessness (restless, unfocused, playing with hands or clothes)
3 Moving about; can't sit still
4 Hand wringing, nail biting, hair pulling, biting of lips, patient is moving about a lot

SECTION 21. HouSehold Food Insecurity Scale (HFIAS)

For each of the following questions, consider what has happened in the last 30 days. Please answer whether this happened never, rarely (once or twice), sometimes (3-10 times), or often (more than 10 times) in the past 30 days.

21.2 Did you worry that your household would not have enough food?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.3 Were you or any household member not able to eat the kinds of foods you preferred because of a lack of resources?

Never [0]

Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.4 Did you or any household member eat just a few kinds of food day after day due to a lack of resources?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.5 Did you or any household member eat food that you preferred not to eat because of a lack of resources to obtain other types of food?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.6 Did you or any household member eat a smaller meal than you felt you needed because there was not enough food?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.7 Did you or any other household member eat fewer meals in a day because there was not enough food?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.8 Was there ever no food at all in your household because there were not enough resources to get more?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.9 Did you or any household member go to sleep at night hungry because there was not enough food?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

21.10 Did you or any household member go a whole day without eating anything because there was not enough food?

Never [0]
Rarely (once or twice in the past 30 days) [1]
Sometimes (three to ten times in the past 30 days) [2]
Often (more than 10 times in the past 30 days) [3]

SECTION 22. Multidimensional Scale of Perceived Social Support

The following questions ask you about a 'special person in your life', 'your family', and 'your friends'. Please tell me if you agree or disagree with these statements. Use the table to help choose the answer. Tick "1" if you Very Strongly Disagree, "2" if you Strongly Disagree, "3" if you Mildly Disagree, "4" if you are Neutral, "5" if you Mildly Agree, "6" if you Strongly Agree, or "7" if you Very Strongly Agree.

1.	**There is a special person who is around when I am in need.**	1	2	3	4	5	6	7	SO
2.	**There is a special person with whom I can share my joys and sorrows.**	1	2	3	4	5	6	7	SO
3.	**My family really tries to help me.**	1	2	3	4	5	6	7	Fam
4.	**I get the emotional help and support I need from my family.**	1	2	3	4	5	6	7	Fam
5.	**I have a special person who is a real source of comfort to me.**	1	2	3	4	5	6	7	SO
6.	**My friends really try to help me.**	1	2	3	4	5	6	7	Fri
7.	**I can count on my friends when things go wrong.**	1	2	3	4	5	6	7	Fri
8.	**I can talk about my problems with my family.**	1	2	3	4	5	6	7	Fam
9.	**I have friends with whom I can share my joys and sorrows.**	1	2	3	4	5	6	7	Fri
10.	**There is a special person in my life who cares about my feelings.**	1	2	3	4	5	6	7	SO
11.	**My family is willing to help me make decisions.**	1	2	3	4	5	6	7	Fam
12.	**I can talk about my problems with my friends.**	1	2	3	4	5	6	7	Fri

SECTION 23. Alcohol, Drug and Sexual Abuse

AUDIT

23.1 Now I am going to ask you some questions about your use of alcoholic beverages during this past year. [Visual cues for a drink - Explain what is meant by alcoholic beverages by using local examples of beer, wine, vodka, etc. Code answers in terms of standard drinks]

23.2 **How often do you have a drink containing alcohol?**

Never [0]
Monthly or less [1]
2-4 times a month [2]
2-3 times a week [3]
4 or more times a week [4]

If response Equals 'Never [0]' then skip to (23.11)

23.3 **How many drinks containing alcohol do you have on a typical day when you are drinking?**

1-2 [0]
3-4 [1]
5-6 [2]
7-9 [3]
10 or more [4]

23.4 **How often do you have six or more drinks on one occasion?**
Never [0]
Less than monthly [1]
Monthly [2]
Weekly [3]
Daily or almost daily [4]
23.6 **How often during the last year have you found that you were not able to stop drinking once you had started?**
Never [0]
Less than monthly [1]
Monthly [2]
Weekly [3]
Daily or almost daily [4]
23.7 **How often during the last year have you failed to do what was normally expected from you because of drinking?**
Never [0]
Less than monthly [1]
Monthly [2]
Weekly [3]
Daily or almost daily [4]
23.8 **How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?**
Never [0]
Less than monthly [1]
Monthly [2]
Weekly [3]
Daily or almost daily [4]
23.9 **How often during the last year have you had a feeling of guilt or remorse after drinking?**
Never [0]
Less than monthly [1]
Monthly [2]
Weekly [3]
Daily or almost daily [4]
23.10 **How often during the last year have you been unable to remember what happened the night before because you had been drinking?**
Never [0]
Less than monthly [1]
Monthly [2]
Weekly [3]
Daily or almost daily [4]
23.11 **Have you or someone else ever been injured as a result of your drinking**?
No [0]
Yes, but not in the last year [2]
Yes, during the last year [4]
23.12 **Has a relative or friend or a doctor or another health worker ever been concerned about your drinking or suggested you cut down?**
No [0]
Yes, but not in the last year [2]
Yes, during the last year [4]

23.13 **DRUGS. Now let's talk briefly about drug use. How often over the past 3 months have you taken drugs, excluding alcohol?**
Never
Once a month or less
2-4 times a month
2-3 times a week
4 or more times a week

23.14 If yes, what kind of drugs did you take? _____

ABUSE:
23.15 Now let's talk about physical and sexual abuse. Have you been a victim of physical violence in the last 3 months? (eg. Beating, pushing, kicking, biting, slapping etc)
Yes
No
23.16 Who abused you physically?
Partner
Relative
Friend
Stranger
Acquaintance
23.17 Have you been a victim of sexual violence in the last 3 months?
Yes
No
23.18 Who abused you sexually?
Partner
Relative
Friend
Stranger
Acquaintance

SECTION 24. HIV Status

24.2 Do you know your HIV status? YES NO
IF NO, SKIP TO 25.1
24.3 What is your HIV status?
Positive
Negative
Refuse to say
24.4 When did you find out your HIV status?
Today
In the last month
In the last 6 months
Longer ago
24.5 Do you know the date of your last HIV test?
Yes
No
Refused

24.6 **What was the date of your most recent HIV test? [DD-MM-YYYY] _____**

SECTION 25.

Contact phone number: _____

Alternative phone numbers: 1. _____ Name and Relationship: _____

2. _____ Name and Relationship: _____

3. _____ Name and Relationship: _____

Section 26.Closing

26.4 **What do you think has caused your depression? (DC: Do not read options out loud, and check all that are mentioned)**

HIV Status [1]
Death of a loved one [2]
Lack of money [3]
Unwanted pregnancy [4]
Partner rejection from the pregnancy [5]
Lack of support from partner [6]
Lack of support from family [7]
Witchcraft [8]
Unemployment [9]
Violence/Abuse [10]
Disagreements with a particular person [11]
Worries about the future (eg. Finance, partner, family, baby) [12]
Other [95]
Don't know [99]

26.8 What is the date of your next clinic visit?

26.9 Thank you for participating in our study. In the next few days a counsellor will phone you and either book an appointment to see you or ask you how you are, on the phone. Please make sure you answer their phone calls. They are trying to help you. Do you have any questions?

Appendix 3: Ethical approval for Affirm study.

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
healthres@pgwc.gov.za
tel: +27 21 483 9907: fax: +27 21 483 9895
1st Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: RP 79/2012
ENQUIRIES: Charlene Roderick

46 Sawkins Road,
Rondebosch,
7700

For attention: Associate Professor Crick Lund

Re: Africa Focus on Intervention Research for Mental Health (AFFIRM)

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries.

Khayelitsha Site B **Mr David Binza** **Contact No. 021 361 4835**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (healthres@pgwc.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely

Signed

DR NT Naledi
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 10/01/2014

CC **DR A HAWKRIDGE** **DIRECTOR: EASTERN/KHAYELITSHA**

Page 1of 1

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
healthres@pgwc.gov.za
tel: +27 21 483 9907: fax: +27 21 483 9895
1st Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: RP 79/2012
ENQUIRIES: Dr Sikhumbuzo Mabunda

46 Sawkins Road,
Rondebosch,
7700

For attention: Associate Professor Crick Lund

Re: Africa Focus on Intervention Research for Mental Health (AFFIRM)

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries.

Michael Mapongwana **Ms Matiyela** **(021) 363 1080**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (healthres@pgwc.gov.za).
3. The reference number above should be quoted in all future correspondence.

We look forward to hearing from you.

Yours sincerely

Signed

DR NT Naledi
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE: 18/7/2012

CC **DR G PEREZ** **DIRECTOR: EASTERN/KHAYELITSHA**

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Appendix 4: Ethical approval for this study

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 **Old Main Building**
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

24 July 2015

HREC REF: 469/2015

A/Prof S Cleary
Public Health & Family Medicine
Health Economics Unit
Falmouth Building

A/Prof Cleary

PROJECT TITLE: A COST-ANALYSIS OF A TASK SHIFTING APPROACH OF A PSYCHOLOGICAL INTERVENTION FOR MATERNAL DEPRESSION AND THE IMPACT OF MATERNAL DEPRESSION ON HEALTH CARE UTILIZATION COSTS IN KHAYELITSHA, SOUTH AFRICA (Masters Candidate – Ms S Orangi) Sub-study linked to 226/2011

Thank you for your response letter dated 17 July 2015, clarifying that informed consent has already been collected in AFFIRM.

It is a pleasure to inform you that the HREC has formally approved the above-mentioned study.

Approval is granted for one year until the 30th July 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the following student:-Stacy Orangi is also involved in this project.

Please quote the HREC reference no in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.

Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

Appendix 5: Journal instructions for authors

Preparing main manuscript text

General guidelines of the journal's style and language are given below.

Overview of manuscript sections for Research Articles

Manuscripts for Research Articles submitted to *Cost Effectiveness and Resource Allocation* should be divided into the following sections (in this order):

- Title page
- Abstract
- Keywords
- Background
- Methods
- Results and discussion
- Conclusions
- List of abbreviations used (if any)
- Competing interests
- Authors' contributions
- Authors' information
- Acknowledgements
- Endnotes
- References
- Illustrations and figures (if any)
- Tables and captions
- Preparing additional files

The **Accession Numbers** of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the corresponding database name; for example, [EMBL:AB098 95, EMBL:AC137000, DDBJ:AE000812, GenBank:U49845, PDB:1BFM, Swiss-Prot:Q96KQ7, PIR:S66116].

The databases for which we can provide direct links are: EMBL Nucleotide Sequence Database (EMBL), DNA Data Bank of Japan (DDBJ), GenBank at the NCBI (GenBank), Protein Data Bank (PDB), Protein Information Resource (PIR) and the Swiss-Prot Protein Database (Swiss-Prot).

For reporting standards please see the information in the About section.

Title page

The title page should:

- provide the title of the article
- list the full names, institutional addresses and email addresses for all authors
- indicate the corresponding author

Please note:

- the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study"
- abbreviations within the title should be avoided
- if a collaboration group should be listed as an author, please list the Group name as an author. If you would like the names of the individual members of the Group to be searchable through their individual PubMed records, please include this information in the "acknowledgements" section in accordance with the instructions below. Please note that the individual names may not be included in the PubMed record at the time a published article is initially included in PubMed as it takes PubMed additional time to code this information.

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background,** the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the CONSORT extension for abstracts.

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where

appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

For studies involving human participants a statement detailing ethical approval and consent should be included in the methods section. For further details of the journal's editorial policies and ethical guidelines see 'About this journal'.
For further details of the journal's data-release policy, see the policy section in 'About this journal'.

Results and discussion

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

Financial competing interests

- In the past three years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.
- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.
- Do you have any other financial competing interests? If so, please specify.

Non-financial competing interests

Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

If you are unsure as to whether you, or one your co-authors, has a competing interest please discuss it with the editorial office.

Authors' contributions

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

According to ICMJE guidelines, An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to be published; and 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, a department chair who provided only general support, or those who contributed as part of a large collaboration group.

Authors' information

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Acknowledgements

Please acknowledge anyone who contributed towards the article by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Please also acknowledge anyone who contributed materials essential for the study. If a language editor has made significant revision of the manuscript, we recommend that you acknowledge the editor by name, where possible.

The role of a scientific (medical) writer must be included in the acknowledgements section, including their source(s) of funding. We suggest wording such as 'We thank Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.'

If you would like the names of the individual members of a collaboration Group to be searchable through their individual PubMed records, please ensure that the title of the collaboration Group is included on the title page and in the submission system and also include collaborating author names as the last paragraph of the “acknowledgements” section. Please add authors in the format First Name, Middle initial(s) (optional), Last Name. You can add institution or country information for each author if you wish, but this should be consistent across all authors.

Please note that individual names may not be present in the PubMed record at the time a published article is initially included in PubMed as it takes PubMed additional time to code this information.

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section.

Endnotes

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

References

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles, clinical trial registration records and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished observations" or "personal communications" giving the names of the involved researchers. Obtaining permission to quote personal communications and unpublished data from the cited colleagues is the responsibility of the author. Footnotes are not allowed, but endnotes are permitted. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should include all named authors, up to the first six before adding 'et al.'..

Any *in press* articles cited within the references and necessary for the reviewers' assessment of the manuscript should be made available if requested by the editorial office.
An Endnote style file is available.
Examples of the *Cost Effectiveness and Resource Allocation* reference style are shown below.
Please ensure that the reference style is followed precisely; if the references are not in the correct style they may have to be retyped and carefully proofread.
All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Authors may wish to make use of reference management software to ensure that reference lists are correctly formatted. An example of such software is Papers, which is part of Springer Science+Business Media.

Examples of the *Cost Effectiveness and Resource Allocation* reference style

Article within a journal
Smith JJ. The world of science. Am J Sci. 1999;36:234-5.
Article within a journal (no page numbers)
Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. BMC Medicine. 2013;11:63.
Article within a journal by DOI
Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. Dig J Mol Med. 2000; doi:10.1007/s801090000086.
Article within a journal supplement
Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. Blood 1979;59 Suppl 1:26-32.
Book chapter, or an article within a book
Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. p. 251-306.
OnlineFirst chapter in a series (without a volume designation but with a DOI)
Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. Top Curr Chem. 2007. doi:10.1007/128_2006_108.

Complete book, authored
Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.
Online document
Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.
Online database
Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998. http://www.healthwise.org. Accessed 21 Sept 1998.
Supplementary material/private homepage
Doe J. Title of supplementary material. 2000. http://www.privatehomepage.com. Accessed 22 Feb 2000.
University site
Doe, J: Title of preprint. http://www.uni-heidelberg.de/mydata.html (1999). Accessed 25 Dec 1999.
FTP site
Doe, J: Trivial HTTP, RFC2169. ftp://ftp.isi.edu/in-notes/rfc2169.txt (1999). Accessed 12 Nov 1999.
Organization site
ISSN International Centre: The ISSN register. http://www.issn.org (2006). Accessed 20 Feb 2007.
Dataset with persistent identifier
Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (Sorghum bicolor). GigaScience Database. 2011. http://dx.doi.org/10.5524/100012.

Preparing illustrations and figures

Illustrations should be provided as separate files, not embedded in the text file. Each figure should include a single illustration and should fit on a single page in portrait format. If a figure consists of separate parts, it is important that a single composite illustration file be submitted which contains all parts of the figure. There is no charge for the use of color figures.

Please read our figure preparation guidelines for detailed instructions on maximising the quality of your figures.

Formats

The following file formats can be accepted:

- PDF (preferred format for diagrams)
- DOCX/DOC (single page only)
- PPTX/PPT (single slide only)
- EPS
- PNG (preferred format for photos or images)
- TIFF
- JPEG
- BMP

Figure legends

The legends should be included in the main manuscript text file at the end of the document, rather than being a part of the figure file. For each figure, the following information should be provided: Figure number (in sequence, using Arabic numerals - i.e. Figure 1, 2, 3 etc); short title of figure (maximum 15 words); detailed legend, up to 300 words.

Please note that it is the responsibility of the author(s) to obtain permission from the copyright holder to reproduce figures or tables that have previously been published elsewhere.

Preparing tables

Each table should be numbered and cited in sequence using Arabic numerals (i.e. Table 1, 2, 3 etc.). Tables should also have a title (above the table) that summarizes the whole table; it should be no longer than 15 words. Detailed legends may then follow, but they should be concise. Tables should always be cited in text in consecutive numerical order.

Smaller tables considered to be integral to the manuscript can be pasted into the end of the document text file, in A4 portrait or landscape format. These will be typeset and displayed in the final published form of the article. Such tables should be formatted using the 'Table object' in a word processing program to ensure that columns of data are kept aligned when the file is sent electronically for review; this will not always be the case if columns are generated by simply using tabs to separate text. Columns and rows of data should be made visibly distinct by ensuring that the borders of each cell display as black lines. Commas should not be used to indicate numerical values. Color and shading may not be used; parts of the table can be highlighted using symbols or bold text, the meaning of which should be explained in a table legend. Tables should not be embedded as figures or spreadsheet files.

Larger datasets or tables too wide for a landscape page can be uploaded separately as additional files. Additional files will not be displayed in the final, laid-out PDF of the article, but a link will be provided to the files as supplied by the author.

Tabular data provided as additional files can be uploaded as an Excel spreadsheet (.xls) or comma separated values (.csv). As with all files, please use the standard file extensions.

Preparing additional files

Although *Cost Effectiveness and Resource Allocation* does not restrict the length and quantity of data included in an article, we encourage authors to provide datasets, tables, movies, or other information as additional files.
Please note: All Additional files **will be published** along with the article. Do not include files such as patient consent forms, certificates of language editing, or revised versions of the main manuscript document with tracked changes. Such files should be sent by email to resource-allocation@biomedcentral.com, quoting the Manuscript ID number.
Results that would otherwise be indicated as "data not shown" can and should be included as additional files. Since many weblinks and URLs rapidly become broken, *Cost Effectiveness and Resource Allocation* requires that supporting data are included as additional files, or deposited in a recognized repository. Please do not link to data on a personal/departmental website. The maximum file size for additional files is 20 MB each, and files will be virus-scanned on submission.

Additional files can be in any format, and will be downloadable from the final published article as supplied by the author. We recommend CSV rather than PDF for tabular data.

Certain supported files formats are recognized and can be displayed to the user in the browser. These include most movie formats (for users with the Quicktime plugin), mini-websites prepared according to our guidelines, chemical structure files (MOL, PDB), geographic data files (KML).

If additional material is provided, please list the following information in a separate section of the manuscript text:

- File name (e.g. Additional file 1)
- File format including the correct file extension for example .pdf, .xls, .txt, .pptx (including name and a URL of an appropriate viewer if format is unusual)
- Title of data
- Description of data

Additional files should be named "Additional file 1" and so on and should be referenced explicitly by file name within the body of the article, e.g. 'An additional movie file shows this in more detail [see Additional file 1]'.

Additional file formats

Ideally, file formats for additional files should not be platform-specific, and should be viewable using free or widely available tools. The following are examples of suitable formats.

- Additional documentation
  - PDF (Adode Acrobat)
- Animations
  - SWF (Shockwave Flash)
- Movies
  - MP4 (MPEG 4)
  - MOV (Quicktime)
- Tabular data
  - XLS, XLSX (Excel Spreadsheet)
  - CSV (Comma separated values)

As with figure files, files should be given the standard file extensions.

Mini-websites

Small self-contained websites can be submitted as additional files, in such a way that they will be browsable from within the full text HTML version of the article. In order to do this, please follow these instructions:

1. Create a folder containing a starting file called index.html (or index.htm) in the root.
2. Put all files necessary for viewing the mini-website within the folder, or sub-folders.

3. Ensure that all links are relative (ie "images/picture.jpg" rather than "/images/picture.jpg" or "http://yourdomain.net/images/picture.jpg" or "C:\Documents and Settings\username\My Documents\mini-website\images\picture.jpg") and no link is longer than 255 characters.

4. Access the index.html file and browse around the mini-website, to ensure that the most commonly used browsers (Internet Explorer and Firefox) are able to view all parts of the mini-website without problems, it is ideal to check this on a different machine.

5. Compress the folder into a ZIP, check the file size is under 20 MB, ensure that index.html is in the root of the ZIP, and that the file has .zip extension, then submit as an additional file with your article.

Style and language

General

Currently, *Cost Effectiveness and Resource Allocation* can only accept manuscripts written in English. Spelling should be US English or British English, but not a mixture.
There is no explicit limit on the length of articles submitted, but authors are encouraged to be concise.

Cost Effectiveness and Resource Allocation will not edit submitted manuscripts for style or language; reviewers may advise rejection of a manuscript if it is compromised by grammatical errors. Authors are advised to write clearly and simply, and to have their article checked by colleagues before submission. In-house copyediting will be minimal. Non-native speakers of English may choose to make use of a copyediting service.

Help and advice on scientific writing

The abstract is one of the most important parts of a manuscript. For guidance, please visit our page on Writing titles and abstracts for scientific articles.
Tim Albert has produced for BioMed Central a list of tips for writing a scientific manuscript. American Scientist also provides a list of resources for science writing. For more detailed guidance on preparing a manuscript and writing in English, please visit the BioMed Central author academy.

Abbreviations

Abbreviations should be used as sparingly as possible. They should be defined when first used and a list of abbreviations can be provided following the main manuscript text.

Typography

- Please use double line spacing.
- Type the text unjustified, without hyphenating words at line breaks.
- Use hard returns only to end headings and paragraphs, not to rearrange lines.
- Capitalize only the first word, and proper nouns, in the title.
- All pages should be numbered.
- Use the *Cost Effectiveness and Resource Allocation* reference format.
- Footnotes are not allowed, but endnotes are permitted.
- Please do not format the text in multiple columns.

- Greek and other special characters may be included. If you are unable to reproduce a particular special character, please type out the name of the symbol in full. **Please ensure that all special characters used are embedded in the text, otherwise they will be lost during conversion to PDF.**

Units

SI units should be used throughout (liter and molar are permitted, however).